Dossier zur Nutzenbewertung gemäß § 35a SGB V

Nivolumab (OPDIVO®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 Y

Anhang 4-G

Erstlinienbehandlung des nicht resezierbaren oder metastasierten Urothelkarzinoms in Kombination mit Cisplatin und Gemcitabin

Ergänzende Analysen

Stand: 19.06.2024

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Table 23.2
Mixed Model Repeated Measures Analysis of EQ-5D-5L VAS
All Randomized Subjects - Arm C and D

EQ-5D-5L Domain	Nivolumab + SOC (N = 304)			SOC (N = 304)			Nivolumab + SOC vs. SOC	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	Difference in Mean Change (95% CI) P-value (2)	SMD as Hedges' g (95% CI) (3)
VAS	273	73.8 (18.2)	1.31 (-0.44, 3.07)	247	74.7 (17.8)	0.39 (-1.68, 2.46)	0.92 (-1.46, 3.31) 0.4479	0.07 (-0.11, 0.24)

June 2023 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(2) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit and treatment*visit week interaction as fixed effects, baseline PRO score, PDL1 status, liver metastasis as covariates, and visit week as repeated effect. Models run using an UN covariance matrix, if any model failed to converge, CS and then AR(1) were used, respectively.
(3) Hedges g = (mean chg nivolumab + SOC - mean chg SOC)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Only the timepoints with 10 subjects or more in each treatment group are included in the analysis.
Positive difference favors nivolumab + SOC, negative difference favors SOC.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-sy-mmrm-ebr2114-b2.sas 11APR2024:05:15:53

Anhang 4-G-1.1.2: Krankheitssymptomatik gemäß EORTC QLQ-C30 – Mittlere Änderung im Vergleich zur Baseline (MMRM)

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Table 23.1
Mixed Model Repeated Measures Analysis of EORTC QLQ-C30
All Randomized Subjects - Arm C and D

EORTC QLQ-C30 Domain	Nivolumab + SOC (N = 304)			SOC (N = 304)			Nivolumab + SOC vs. SOC	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	Difference in Mean Change (95% CI) P-value (2)	SMD as Hedges' g (95% CI) (3)
FATIGUE	276	28.0 (23.3)	3.37 (1.07, 5.68)	247	27.3 (23.7)	5.14 (2.40, 7.89)	-1.77 (-4.94, 1.40) 0.2735	-0.10 (-0.27, 0.08)
NAUSEA AND VOMITING	276	4.4 (13.0)	5.99 (4.19, 7.80)	247	5.3 (13.5)	4.63 (2.46, 6.80)	1.36 (-1.16, 3.89) 0.2897	0.09 (-0.08, 0.26)
PAIN	276	26.4 (26.9)	-7.85 (-10.12, -5.57)	248	28.3 (29.0)	-6.72 (-9.51, -3.93)	-1.12 (-4.30, 2.05) 0.4872	-0.06 (-0.23, 0.11)
DYSPNEA	275	13.2 (24.3)	2.48 (0.20, 4.76)	246	11.1 (18.9)	4.08 (1.32, 6.84)	-1.60 (-4.80, 1.59) 0.3249	-0.09 (-0.26, 0.09)
INSOMNIA	275	27.4 (29.3)	-7.00 (-9.66, -4.35)	247	26.7 (29.5)	-6.94 (-10.13, -3.76)	-0.06 (-3.71, 3.59) 0.9740	0.00 (-0.17, 0.17)
APPETITE LOSS	276	17.3 (26.0)	0.80 (-1.79, 3.39)	248	18.4 (26.9)	-1.31 (-4.46, 1.83)	2.11 (-1.48, 5.71) 0.2491	0.10 (-0.07, 0.27)

June 2023 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(2) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit and treatment*visit week interaction as fixed effects, baseline PRO score, PDL1 status, liver metastasis as covariates, and visit week as repeated effect. Models run using an UN covariance matrix, if any model failed to converge, CS and then AR(1) were used, respectively.
(3) Hedges g = (mean chg nivolumab + SOC - mean chg SOC)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Only the timepoints with 10 subjects or more in each treatment group are included in the analysis.
Functional scale/Global Health Status/QOL: Positive difference favors nivolumab + SOC, negative difference favors SOC.
Symptom scale/item: negative difference favors nivolumab + SOC, positive difference favors SOC.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-sy-mmrm-ebr2114-b2.sas 11APR2024:05:15:58

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Table 23.1
Mixed Model Repeated Measures Analysis of EORTC QLQ-C30
All Randomized Subjects - Arm C and D

EORTC QLQ-C30 Domain	Nivolumab + SOC (N = 304)			SOC (N = 304)			Nivolumab + SOC vs. SOC	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	Difference in Mean Change (95% CI) P-value (2)	SMD as Hedges' g (95% CI) (3)
CONSTIPATION	276	17.0 (26.6)	-2.36 (-4.92, 0.19)	245	18.4 (28.0)	-2.03 (-5.10, 1.04)	-0.33 (-3.83, 3.17) 0.8518	-0.02 (-0.19, 0.16)
DIARRHEA	275	5.8 (15.5)	-1.35 (-2.66, -0.04)	245	5.4 (15.3)	0.97 (-0.63, 2.57)	-2.31 (-4.15, -0.48) 0.0137	-0.22 (-0.39, -0.04)

June 2023 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(2) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit and treatment*visit week interaction as fixed effects, baseline PRO score, PDL1 status, liver metastasis as covariates, and visit week as repeated effect. Models run using an UN covariance matrix, if any model failed to converge, CS and then AR(1) were used, respectively.
(3) Hedges g = (mean chg nivolumab + SOC - mean chg SOC)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Only the timepoints with 10 subjects or more in each treatment group are included in the analysis.
Functional scale/Global Health Status/QOL: Positive difference favors nivolumab + SOC, negative difference favors SOC.
Symptom scale/item: negative difference favors nivolumab + SOC, positive difference favors SOC.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-sy-mmrm-ebr2114-b2.sas 11APR2024:05:15:58

Anhang 4-G-1.2: Endpunkte Lebensqualität – Zusatzanalysen

Anhang 4-G-1.2.1: Globaler Gesundheitsstatus und Funktionsskalen gemäß EORTC QLQ-C30 – Mittlere Änderung im Vergleich zur Baseline (MMRM)

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Table 23.1
Mixed Model Repeated Measures Analysis of EORTC QLQ-C30
All Randomized Subjects - Arm C and D

EORTC QLQ-C30 Domain	Nivolumab + SOC (N = 304)			SOC (N = 304)			Nivolumab + SOC vs. SOC	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (2)	Difference in Mean Change (95% CI) P-value (2)	SMD as Hedges' g (95% CI) (3)
PHYSICAL FUNCTIONING	276	82.3 (18.8)	-1.89 (-3.74, -0.03)	246	83.0 (17.8)	-3.43 (-5.63, -1.24)	1.55 (-0.98, 4.08) 0.2292	0.11 (-0.07, 0.28)
ROLE FUNCTIONING	275	78.1 (26.0)	-2.70 (-5.36, -0.05)	248	78.5 (27.1)	-5.83 (-8.98, -2.68)	3.12 (-0.53, 6.78) 0.0934	0.15 (-0.03, 0.32)
EMOTIONAL FUNCTIONING	276	78.2 (19.4)	3.94 (2.07, 5.81)	245	77.5 (20.3)	4.73 (2.39, 7.07)	-0.79 (-3.46, 1.89) 0.5625	-0.05 (-0.22, 0.12)
COGNITIVE FUNCTIONING	276	87.9 (15.8)	-0.32 (-2.05, 1.41)	245	88.1 (17.5)	-0.46 (-2.65, 1.72)	0.14 (-2.34, 2.62) 0.9111	0.01 (-0.16, 0.18)
SOCIAL FUNCTIONING	276	79.2 (25.3)	0.36 (-1.85, 2.57)	245	78.3 (26.7)	-1.43 (-4.10, 1.24)	1.79 (-1.28, 4.86) 0.2523	0.10 (-0.07, 0.27)
GLOBAL HEALTH STATUS	276	66.4 (22.6)	0.37 (-1.59, 2.33)	245	67.1 (22.1)	-1.01 (-3.42, 1.40)	1.38 (-1.38, 4.14) 0.3267	0.09 (-0.09, 0.26)

June 2023 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(2) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit and treatment*visit week interaction as fixed effects, baseline PRO score, PDL1 status, liver metastasis as covariates, and visit week as repeated effect. Models run using an UN covariance matrix, if any model failed to converge, CS and then AR(1) were used, respectively.
(3) Hedges g = (mean chg nivolumab + SOC - mean chg SOC)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Only the timepoints with 10 subjects or more in each treatment group are included in the analysis.
Functional scale/Global Health Status/QOL: Positive difference favors nivolumab + SOC, negative difference favors SOC.
Symptom scale/item: negative difference favors nivolumab + SOC, positive difference favors SOC.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-sy-mmrm-ebr2114-b2.sas 11APR2024:05:15:58

Anhang 4-G-1.3: Endpunkte Verträglichkeit – Weitere Analysen

Anhang 4-G-1.3.1: Ergebnisse für UESI

Anhang 4-G-1.3.1.1: Ergebnisse für imUE

Anhang 4-G-1.3.1.1.1: Jegliche imUE

Protocol: CA209901

Table 13.1.1
Immune-mediated Adverse Events: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Immune-mediated Adverse Events (IMAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH ANY IMMUNE-MEDIATED AES	304	89 (29.3)	N.A.	288	2 (0.7)	N.A.	35.501 (8.714, >99.999)	<0.0001
SUBJECTS WITH PNEUMONITIS	304	5 (1.6)	N.A.	288	0	N.E.	N.E.	0.0663
SUBJECTS WITH DIARRHEA/COLITIS	304	4 (1.3)	N.A.	288	0	N.E.	N.E.	0.3766
SUBJECTS WITH HEPATITIS	304	4 (1.3)	N.A.	288	0	N.E.	N.E.	0.1812
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION	304	4 (1.3)	N.A.	288	0	N.E.	N.E.	0.1640
SUBJECTS WITH RASH	304	26 (8.6)	47.84 (N.A., N.A.)	288	2 (0.7)	N.A.	8.135 (1.887, 35.068)	0.0008
SUBJECTS WITH HYPERSENSITIVITY	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.4142
SUBJECTS WITH ADRENAL INSUFFICIENCY	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.7115
SUBJECTS WITH HYPOPHYSITIS	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.2159
SUBJECTS WITH HYPOTHYROIDISM/THYROIDITIS	304	40 (13.2)	N.A.	288	0	N.E.	N.E.	<0.0001

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:22

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Table 13.1.1
Immune-mediated Adverse Events: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Immune-mediated Adverse Events (IMAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH HYPOTHYROIDISM	304	39 (12.8)	N.A.	288	0	N.E.	N.E.	<0.0001
SUBJECTS WITH THYROIDITIS	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.3328
SUBJECTS WITH HYPERTHYROIDISM	304	22 (7.2)	N.A.	288	0	N.E.	N.E.	<0.0001
SUBJECTS WITH DIABETES MELLITUS	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	N.A.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:22

Anhang 4-G-1.3.1.1.2: Schwere imUE

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Table 13.1.2
Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Immune-mediated Adverse Events (IMAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH IMMUNE-MEDIATED AES CTCAE GRADES >= 3	304	20 (6.6)	N.A.	288	0	N.E.	N.E.	0.0066
SUBJECTS WITH PNEUMONITIS	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.3598
SUBJECTS WITH DIARRHEA/COLITIS	304	4 (1.3)	N.A.	288	0	N.E.	N.E.	0.5509
SUBJECTS WITH HEPATITIS	304	4 (1.3)	N.A.	288	0	N.E.	N.E.	0.1824
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.3262
SUBJECTS WITH RASH	304	4 (1.3)	N.A.	288	0	N.E.	N.E.	0.1751
SUBJECTS WITH HYPERSENSITIVITY	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH ADRENAL INSUFFICIENCY	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.9062
SUBJECTS WITH HYPOPHYSITIS	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.4046
SUBJECTS WITH HYPOTHYROIDISM/THYROIDITIS	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:27

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Table 13.1.2
Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Immune-mediated Adverse Events (IMAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH HYPOTHYROIDISM	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH THYROIDITIS	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH HYPERTHYROIDISM	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.3243
SUBJECTS WITH DIABETES MELLITUS	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:27

Anhang 4-G-1.3.1.1.3: Schwerwiegende imUE

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Table 13.1.3
Serious Immune-mediated Adverse Events : Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Immune-mediated Adverse Events (IMAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH SERIOUS IMMUNE-MEDIATED AES	304	18 (5.9)	N.A.	288	0	N.E.	N.E.	0.0065
SUBJECTS WITH PNEUMONITIS	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.3598
SUBJECTS WITH DIARRHEA/COLITIS	304	4 (1.3)	N.A.	288	0	N.E.	N.E.	0.5657
SUBJECTS WITH HEPATITIS	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.3372
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.3262
SUBJECTS WITH RASH	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.1643
SUBJECTS WITH HYPERSENSITIVITY	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH ADRENAL INSUFFICIENCY	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.9062
SUBJECTS WITH HYPOPHYSITIS	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.2159
SUBJECTS WITH HYPOTHYROIDISM/THYROIDITIS	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:32

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Table 13.1.3
Serious Immune-mediated Adverse Events : Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Immune-mediated Adverse Events (IMAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH HYPOTHYROIDISM	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH THYROIDITIS	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH HYPERTHYROIDISM	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.3308
SUBJECTS WITH DIABETES MELLITUS	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	N.A.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:32

Anhang 4-G-1.3.1.2: Ergebnisse für spezifische UE

Anhang 4-G-1.3.1.2.1: Jegliche spezifische UE

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Table 13.1
Select Adverse Events: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Select Adverse Events (SLAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH ANY SELECT AES	304	227 (74.7)	2.53 (2.07, 3.68)	288	141 (49.0)	5.78 (2.92, N.A.)	1.545 (1.249, 1.911)	<0.0001
SUBJECTS WITH ENDOCRINE AES	304	68 (22.4)	N.A.	288	4 (1.4)	N.A.	13.760 (4.997, 37.887)	<0.0001
SUBJECTS WITH GASTROINTESTINAL AES	304	61 (20.1)	N.A.	288	43 (14.9)	N.A.	1.116 (0.748, 1.666)	0.5892
SUBJECTS WITH HEPATIC AES	304	57 (18.8)	N.A.	288	32 (11.1)	N.A.	1.265 (0.805, 1.989)	0.3071
SUBJECTS WITH PULMONARY AES	304	9 (3.0)	N.A.	288	1 (0.3)	N.A.	4.687 (0.559, 39.321)	0.1183
SUBJECTS WITH RENAL AES	304	93 (30.6)	N.A.	288	76 (26.4)	N.A.	0.987 (0.722, 1.348)	0.9367
SUBJECTS WITH SKIN AES	304	117 (38.5)	18.63 (12.94, N.A.)	288	29 (10.1)	N.A.	3.484 (2.306, 5.265)	<0.0001
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	304	14 (4.6)	N.A.	288	10 (3.5)	N.A.	1.008 (0.428, 2.375)	0.9857

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114.sas 29FEB2024:11:07:58

Anhang 4-G-1.3.1.2.2: Schwere spezifische UE

Protocol: CA209901

Table 13.2
Select Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Select Adverse Events (SLAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH SELECT AES CTCAE GRADES >= 3	304	56 (18.4)	N.A.	288	16 (5.6)	N.A.	2.599 (1.464, 4.614)	0.0007
SUBJECTS WITH ENDOCRINE AES	304	4 (1.3)	N.A.	288	1 (0.3)	N.A.	1.777 (0.165, 19.194)	0.6315
SUBJECTS WITH GASTROINTESTINAL AES	304	8 (2.6)	N.A.	288	0	N.E.	N.E.	0.0530
SUBJECTS WITH HEPATIC AES	304	18 (5.9)	N.A.	288	4 (1.4)	N.A.	3.305 (1.092, 10.004)	0.0251
SUBJECTS WITH PULMONARY AES	304	4 (1.3)	N.A.	288	1 (0.3)	N.A.	1.858 (0.171, 20.151)	0.6049
SUBJECTS WITH RENAL AES	304	20 (6.6)	N.A.	288	9 (3.1)	N.A.	1.781 (0.797, 3.978)	0.1540
SUBJECTS WITH SKIN AES	304	8 (2.6)	N.A.	288	1 (0.3)	N.A.	5.760 (0.694, 47.783)	0.0664
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114.sas 29FEB2024:11:08:02

Anhang 4-G-1.3.1.2.3: Schwerwiegende spezifische UE

Protocol: CA209901 Page 1 of 1

Table 13.3
Serious Select Adverse Events : Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Select Adverse Events (SLAE)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH SERIOUS SELECT AES	304	36 (11.8)	N.A.	288	13 (4.5)	N.A.	1.789 (0.917, 3.491)	0.0839
SUBJECTS WITH ENDOCRINE AES	304	6 (2.0)	N.A.	288	1 (0.3)	N.A.	2.609 (0.274, 24.871)	0.3875
SUBJECTS WITH GASTROINTESTINAL AES	304	4 (1.3)	N.A.	288	1 (0.3)	N.A.	0.644 (0.048, 8.634)	0.7387
SUBJECTS WITH HEPATIC AES	304	5 (1.6)	N.A.	288	1 (0.3)	N.A.	2.177 (0.217, 21.835)	0.4995
SUBJECTS WITH PULMONARY AES	304	3 (1.0)	N.A.	288	1 (0.3)	N.A.	0.929 (0.063, 13.752)	0.9572
SUBJECTS WITH RENAL AES	304	16 (5.3)	N.A.	288	9 (3.1)	N.A.	1.440 (0.624, 3.324)	0.3901
SUBJECTS WITH SKIN AES	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.0842
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.3308

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114.sas 29FEB2024:11:08:05

Anhang 4-G-1.3.1.3: Ergebnisse für OESI

Anhang 4-G-1.3.1.3.1: Jegliche OESI

Protocol: CA209901

Table 13.2.1
Other Events of Special Interest: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Other Events of Special Interest (OESI)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH ANY OESI	304	9 (3.0)	N.A.	288	1 (0.3)	N.A.	4.507 (0.526, 38.577)	0.1319
SUBJECTS WITH MYASTHENIC SYNDROME	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH DEMYELINATION EVENT	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.3273
SUBJECTS WITH UVEITIS EVENT	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.9174
SUBJECTS WITH MYOCARDITIS EVENT	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.0984
SUBJECTS WITH MYOSITIS/RHABDOMYOLYSIS EVENT	304	1 (0.3)	N.A.	288	1 (0.3)	N.A.	<0.001 (<0.001, N.A.)	0.3037
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:37

Protocol: CA209901 Page 2 of 2

Table 13.2.1
Other Events of Special Interest: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Other Events of Special Interest (OESI)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH AUTOIMMUNE CYTOPENIA	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.3865
SUBJECTS WITH AUTOIMMUNE EYE DISORDER	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH IMMUNE-MEDIATED ARTHRITIS	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:37

Anhang 4-G-1.3.1.3.2: Schwere OESI

Protocol: CA209901 Page 1 of 2

Table 13.2.2
Other Events of Special Interest with CTCAE Grade 3-4-5: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Other Events of Special Interest (OESI)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH OESI CTCAE GRADES >= 3	304	8 (2.6)	N.A.	288	1 (0.3)	N.A.	3.593 (0.402, 32.144)	0.2216
SUBJECTS WITH MYASTHENIC SYNDROME	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH DEMYELINATION EVENT	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.3273
SUBJECTS WITH UVEITIS EVENT	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.9174
SUBJECTS WITH MYOCARDITIS EVENT	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.1781
SUBJECTS WITH MYOSITIS/RHABDOMYOLYSIS EVENT	304	1 (0.3)	N.A.	288	1 (0.3)	N.A.	<0.001 (<0.001, N.A.)	0.3033
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:42

Table 13.2.2
Other Events of Special Interest with CTCAE Grade 3-4-5: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Other Events of Special Interest (OESI)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH AUTOIMMUNE CYTOPENIA	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.3865
SUBJECTS WITH AUTOIMMUNE EYE DISORDER	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH IMMUNE-MEDIATED ARTHRITIS	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:42

Anhang 4-G-1.3.1.3.3: Schwerwiegende OESI

Protocol: CA209901 Page 1 of 2

Table 13.2.3
Serious Other Events of Special Interest: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Other Events of Special Interest (OESI)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH SERIOUS OESI	304	8 (2.6)	N.A.	288	1 (0.3)	N.A.	4.506 (0.526, 38.567)	0.1320
SUBJECTS WITH MYASTHENIC SYNDROME	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH DEMYELINATION EVENT	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	304	2 (0.7)	N.A.	288	0	N.E.	N.E.	0.3273
SUBJECTS WITH UVEITIS EVENT	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.9174
SUBJECTS WITH MYOCARDITIS EVENT	304	3 (1.0)	N.A.	288	0	N.E.	N.E.	0.0984
SUBJECTS WITH MYOSITIS/RHABDOMYOLYSIS EVENT	304	1 (0.3)	N.A.	288	1 (0.3)	N.A.	<0.001 (<0.001, N.A.)	0.3033
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:47

Protocol: CA209901 Page 2 of 2

Table 13.2.3
Serious Other Events of Special Interest: Time-Adjusted Analyses
On Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Other Events of Special Interest (OESI)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	N	Subjects with Event n (%)	KME [95%CI] (mon) (1)	HR [95%CI] (2)	P-value (3)
SUBJECTS WITH AUTOIMMUNE CYTOPENIA	304	1 (0.3)	N.A.	288	0	N.E.	N.E.	0.3865
SUBJECTS WITH AUTOIMMUNE EYE DISORDER	304	0	N.E.	288	0	N.E.	N.E.	N.E.
SUBJECTS WITH IMMUNE-MEDIATED ARTHRITIS	304	0	N.E.	288	0	N.E.	N.E.	N.E.

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC
(3) Log-rank test stratified by PDL1 status, liver metastasis as entered in IRT
MedDRA Version: 26.0; CTC Version 4
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-slaetahrt-ebr2114-b1p3.sas 15APR2024:09:13:47

Anhang 4-G-1.3.2: Ergebnisse für häufige UE auf SOC/PT-Ebene

Anhang 4-G-1.3.2.1: Häufige jegliche UE auf SOC/PT-Ebene

Protocol: CA209901

Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	304	303 (99.7)	0.13 (0.10, 0.16)	288	287 (99.7)	0.13 (0.10, 0.20)	0.975 (0.828, 1.149)	0.7052
BLOOD AND LYMPHATIC SYSTEM DISORDERS	304	239 (78.6)	1.41 (0.95, 1.64)	288	209 (72.6)	1.12 (0.92, 1.64)	1.083 (0.899, 1.306)	0.4038
ANAEMIA	304	194 (63.8)	2.30 (1.87, 2.79)	288	163 (56.6)	2.96 (2.33, 3.65)	1.147 (0.931, 1.415)	0.2003
NEUTROPENIA	304	105 (34.5)	N.A.	288	89 (30.9)	N.A.	1.081 (0.814, 1.434)	0.5846
THROMBOCYTOPENIA	304	54 (17.8)	N.A.	288	36 (12.5)	N.A.	1.337 (0.872, 2.049)	0.1805
LEUKOPENIA	304	42 (13.8)	N.A.	288	33 (11.5)	N.A.	1.200 (0.761, 1.893)	0.4327
GASTROINTESTINAL DISORDERS	304	239 (78.6)	0.69 (0.26, 0.92)	288	208 (72.2)	0.69 (0.30, 0.89)	1.030 (0.854, 1.242)	0.7344
NAUSEA	304	159 (52.3)	3.94 (2.17, N.A.)	288	153 (53.1)	2.43 (1.84, N.A.)	0.914 (0.731, 1.143)	0.4353
CONSTIPATION	304	92 (30.3)	N.A.	288	81 (28.1)	N.A.	1.002 (0.742, 1.354)	0.9794

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-taesocpthrta-ebr2114-b2.sas 15MAR2024:12:37:47

Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
VOMITING	304	70 (23.0)	47.51 (N.A., N.A.)	288	58 (20.1)	N.A.	1.009 (0.707, 1.441)	0.9647
DIARRHOEA	304	59 (19.4)	N.A.	288	43 (14.9)	N.A.	1.106 (0.740, 1.654)	0.6188
ABDOMINAL PAIN	304	26 (8.6)	N.A.	288	18 (6.3)	N.A.	0.821 (0.425, 1.588)	0.5578
ABDOMINAL PAIN UPPER	304	15 (4.9)	N.A.	288	9 (3.1)	N.A.	1.214 (0.516, 2.856)	0.6570
DYSPEPSIA	304	14 (4.6)	N.A.	288	8 (2.8)	N.A.	1.508 (0.625, 3.637)	0.3568
STOMATITIS	304	13 (4.3)	N.A.	288	9 (3.1)	N.A.	1.194 (0.497, 2.873)	0.6920
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	304	209 (68.8)	1.71 (1.05, 2.33)	288	172 (59.7)	1.91 (1.18, 3.15)	1.125 (0.917, 1.381)	0.2628
FATIGUE	304	87 (28.6)	47.51 (N.A., N.A.)	288	78 (27.1)	N.A.	0.993 (0.729, 1.352)	0.9618
ASTHENIA	304	68 (22.4)	N.A.	288	60 (20.8)	N.A.	1.029 (0.725, 1.461)	0.8756

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-taesocpthrta-ebr2114-b2.sas 15MAR2024:12:37:47

Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
OEDEMA PERIPHERAL	304	45 (14.8)	N.A.	288	25 (8.7)	15.01 (N.A., N.A.)	1.388 (0.836, 2.305)	0.2045
PYREXIA	304	44 (14.5)	N.A.	288	40 (13.9)	N.A.	0.874 (0.562, 1.358)	0.5491
MALAISE	304	19 (6.3)	N.A.	288	12 (4.2)	N.A.	1.516 (0.736, 3.122)	0.2562
PAIN	304	10 (3.3)	N.A.	288	9 (3.1)	N.A.	0.825 (0.322, 2.113)	0.6882
INVESTIGATIONS	304	201 (66.1)	2.37 (1.68, 3.15)	288	157 (54.5)	3.42 (2.33, 4.67)	1.145 (0.926, 1.417)	0.2063
NEUTROPHIL COUNT DECREASED	304	79 (26.0)	N.A.	288	60 (20.8)	N.A.	1.241 (0.886, 1.738)	0.2082
PLATELET COUNT DECREASED	304	68 (22.4)	N.A.	288	47 (16.3)	N.A. (10.58, N.A.)	1.376 (0.947, 2.000)	0.0917
BLOOD CREATININE INCREASED	304	65 (21.4)	N.A.	288	52 (18.1)	N.A.	1.077 (0.743, 1.562)	0.6933
WHITE BLOOD CELL COUNT DECREASED	304	65 (21.4)	N.A.	288	41 (14.2)	N.A.	1.579 (1.068, 2.334)	0.0213*

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
AMYLASE INCREASED	304	34 (11.2)	N.A.	288	15 (5.2)	N.A.	1.928 (1.040, 3.574)	0.0340*
WEIGHT DECREASED	304	33 (10.9)	N.A.	288	16 (5.6)	N.A.	1.595 (0.863, 2.947)	0.1333
ALANINE AMINOTRANSFERASE INCREASED	304	32 (10.5)	N.A.	288	16 (5.6)	N.A.	1.514 (0.814, 2.818)	0.1869
LIPASE INCREASED	304	31 (10.2)	27.66 (N.A., N.A.)	288	13 (4.5)	N.A.	1.511 (0.757, 3.016)	0.2384
ASPARTATE AMINOTRANSFERASE INCREASED	304	30 (9.9)	N.A.	288	15 (5.2)	N.A.	1.496 (0.788, 2.839)	0.2150
LYMPHOCYTE COUNT DECREASED	304	16 (5.3)	N.A.	288	12 (4.2)	N.A.	1.246 (0.589, 2.636)	0.5653
BLOOD THYROID STIMULATING HORMONE INCREASED	304	15 (4.9)	N.A.	288	1 (0.3)	N.A.	8.080 (1.033,63.196)	0.0182*
BLOOD ALKALINE PHOSPHATASE INCREASED	304	14 (4.6)	N.A.	288	11 (3.8)	N.A.	0.850 (0.366, 1.973)	0.7050
BLOOD MAGNESIUM DECREASED	304	12 (3.9)	N.A.	288	2 (0.7)	N.A.	3.417 (0.718,16.257)	0.1014

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
BLOOD GLUCOSE INCREASED	304	10 (3.3)	N.A.	288	6 (2.1)	N.A.	1.015 (0.345, 2.988)	0.9786
METABOLISM AND NUTRITION DISORDERS	304	163 (53.6)	6.64 (3.94, 13.96)	288	118 (41.0)	N.A.	1.230 (0.967, 1.566)	0.0881
DECREASED APPETITE	304	94 (30.9)	N.A.	288	57 (19.8)	N.A.	1.484 (1.063, 2.070)	0.0188*
HYPONATRAEMIA	304	37 (12.2)	46.06 (N.A., N.A.)	288	26 (9.0)	N.A.	1.155 (0.689, 1.936)	0.5851
HYPOKALAEMIA	304	23 (7.6)	N.A.	288	18 (6.3)	N.A.	1.014 (0.538, 1.910)	0.9656
HYPERGLYCAEMIA	304	21 (6.9)	N.A.	288	14 (4.9)	N.A.	1.025 (0.501, 2.093)	0.9455
HYPOMAGNESAEMIA	304	21 (6.9)	N.A.	288	33 (11.5)	N.A.	0.553 (0.318, 0.964)	0.0341*
HYPOALBUMINAEMIA	304	15 (4.9)	N.A.	288	15 (5.2)	N.A.	0.892 (0.434, 1.832)	0.7564
DEHYDRATION	304	14 (4.6)	N.A.	288	5 (1.7)	N.A.	1.789 (0.612, 5.231)	0.2817

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
HYPERKALAEMIA	304	12 (3.9)	N.A.	288	10 (3.5)	N.A.	0.979 (0.416, 2.303)	0.9609
HYPOCALCAEMIA	304	10 (3.3)	N.A.	288	9 (3.1)	N.A.	0.852 (0.334, 2.174)	0.7382
INFECTIONS AND INFESTATIONS	304	147 (48.4)	11.70 (8.51, 20.83)	288	96 (33.3)	N.A.	1.170 (0.896, 1.529)	0.2477
URINARY TRACT INFECTION	304	48 (15.8)	N.A.	288	50 (17.4)	N.A.	0.735 (0.487, 1.111)	0.1439
COVID-19	304	24 (7.9)	N.A.	288	8 (2.8)	N.A.	1.362 (0.560, 3.310)	0.4935
PNEUMONIA	304	14 (4.6)	N.A.	288	10 (3.5)	N.A.	0.641 (0.251, 1.640)	0.3504
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	304	139 (45.7)	12.94 (7.85, N.A.)	288	61 (21.2)	N.A.	2.015 (1.483, 2.736)	<0.0001*
PRURITUS	304	54 (17.8)	N.A.	288	10 (3.5)	N.A.	3.740 (1.874, 7.464)	<0.0001*
RASH	304	52 (17.1)	N.A.	288	16 (5.6)	N.A.	2.505 (1.414, 4.441)	0.0011*

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
ALOPECIA	304	22 (7.2)	N.A.	288	27 (9.4)	N.A.	0.695 (0.392, 1.233)	0.2120
DRY SKIN	304	13 (4.3)	N.A.	288	1 (0.3)	N.A.	10.846 (1.407,83.616)	0.0042*
NERVOUS SYSTEM DISORDERS	304	125 (41.1)	N.A. (10.22, N.A.)	288	81 (28.1)	10.58 (10.58, N.A.)	1.384 (1.042, 1.836)	0.0238*
HEADACHE	304	31 (10.2)	N.A.	288	15 (5.2)	N.A.	1.872 (1.004, 3.490)	0.0452*
DIZZINESS	304	24 (7.9)	N.A.	288	18 (6.3)	N.A.	0.970 (0.510, 1.843)	0.9280
NEUROPATHY PERIPHERAL	304	23 (7.6)	N.A.	288	17 (5.9)	N.A.	1.124 (0.595, 2.123)	0.7187
DYSGEUSIA	304	22 (7.2)	N.A.	288	12 (4.2)	N.A.	1.596 (0.785, 3.247)	0.1928
PERIPHERAL SENSORY NEUROPATHY	304	17 (5.6)	N.A.	288	8 (2.8)	N.A. (10.58, N.A.)	1.484 (0.624, 3.533)	0.3692
PARAESTHESIA	304	16 (5.3)	N.A.	288	17 (5.9)	N.A.	0.810 (0.407, 1.612)	0.5490

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	304	110 (36.2)	24.87 (16.69, N.A.)	288	69 (24.0)	N.A.	1.142 (0.835, 1.563)	0.4047
BACK PAIN	304	39 (12.8)	N.A.	288	31 (10.8)	N.A.	0.844 (0.512, 1.391)	0.5057
ARTHRALGIA	304	33 (10.9)	N.A.	288	11 (3.8)	N.A.	1.879 (0.920, 3.836)	0.0783
MYALGIA	304	17 (5.6)	N.A.	288	5 (1.7)	N.A.	2.631 (0.954, 7.255)	0.0523
PAIN IN EXTREMITY	304	15 (4.9)	33.51 (33.51, N.A.)	288	13 (4.5)	N.A.	0.728 (0.328, 1.613)	0.4324
RENAL AND URINARY DISORDERS	304	106 (34.9)	N.A. (19.55, N.A.)	288	72 (25.0)	N.A.	1.106 (0.810, 1.510)	0.5260
HAEMATURIA	304	35 (11.5)	N.A.	288	24 (8.3)	N.A.	1.056 (0.613, 1.820)	0.8442
ACUTE KIDNEY INJURY	304	24 (7.9)	N.A.	288	18 (6.3)	N.A.	1.025 (0.543, 1.935)	0.9390
DYSURIA	304	13 (4.3)	N.A.	288	10 (3.5)	N.A.	0.805 (0.329, 1.973)	0.6349

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
RENAL FAILURE	304	13 (4.3)	N.A.	288	7 (2.4)	N.A.	1.573 (0.619, 3.998)	0.3368
POLLAKIURIA	304	10 (3.3)	N.A.	288	4 (1.4)	N.A.	1.853 (0.560, 6.131)	0.3050
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	304	101 (33.2)	47.51 (N.A., N.A.)	288	63 (21.9)	N.A.	1.392 (1.008, 1.920)	0.0441*
COUGH	304	26 (8.6)	47.51 (N.A., N.A.)	288	12 (4.2)	N.A.	1.658 (0.817, 3.366)	0.1572
DYSPNOEA	304	23 (7.6)	N.A.	288	14 (4.9)	N.A.	1.503 (0.769, 2.938)	0.2302
HICCUPS	304	18 (5.9)	N.A.	288	8 (2.8)	N.A.	2.162 (0.940, 4.972)	0.0624
PULMONARY EMBOLISM	304	18 (5.9)	N.A.	288	19 (6.6)	N.A.	0.843 (0.440, 1.615)	0.6098
VASCULAR DISORDERS	304	85 (28.0)	N.A.	288	53 (18.4)	N.A.	1.321 (0.928, 1.880)	0.1225
HYPERTENSION	304	25 (8.2)	N.A.	288	12 (4.2)	N.A.	1.225 (0.580, 2.588)	0.5944

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(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
HYPOTENSION	304	20 (6.6)	N.A.	288	6 (2.1)	N.A.	2.473 (0.968, 6.316)	0.0503
DEEP VEIN THROMBOSIS	304	12 (3.9)	N.A.	288	7 (2.4)	N.A.	1.569 (0.617, 3.992)	0.3402
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	304	62 (20.4)	N.A.	288	31 (10.8)	N.A.	1.057 (0.663, 1.686)	0.8151
MALIGNANT NEOPLASM PROGRESSION	304	47 (15.5)	N.A.	288	23 (8.0)	N.A.	1.092 (0.637, 1.870)	0.7488
ENDOCRINE DISORDERS	304	59 (19.4)	N.A.	288	0	N.E.	N.E.	<0.0001*
HYPOTHYROIDISM	304	41 (13.5)	N.A.	288	0	N.E.	N.E.	<0.0001*
HYPERTHYROIDISM	304	22 (7.2)	N.A.	288	0	N.E.	N.E.	<0.0001*
PSYCHIATRIC DISORDERS	304	40 (13.2)	N.A.	288	29 (10.1)	N.A.	1.021 (0.619, 1.684)	0.9363
INSOMNIA	304	19 (6.3)	N.A.	288	15 (5.2)	N.A.	1.019 (0.505, 2.053)	0.9586
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	304	37 (12.2)	N.A.	288	15 (5.2)	N.A.	1.468 (0.776, 2.776)	0.2351

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(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Protocol: CA209901

Table 24.1
Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
EAR AND LABYRINTH DISORDERS	304	36 (11.8)	N.A.	288	30 (10.4)	N.A.	0.960 (0.584, 1.579)	0.8725
TINNITUS	304	19 (6.3)	N.A.	288	20 (6.9)	N.A.	0.819 (0.433, 1.549)	0.5390
CARDIAC DISORDERS	304	23 (7.6)	N.A.	288	12 (4.2)	N.A.	1.690 (0.835, 3.421)	0.1397
EYE DISORDERS	304	22 (7.2)	N.A.	288	9 (3.1)	N.A.	1.842 (0.833, 4.076)	0.1257
HEPATOBILIARY DISORDERS	304	17 (5.6)	N.A.	288	4 (1.4)	N.A.	2.646 (0.854, 8.197)	0.0801
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	304	17 (5.6)	N.A.	288	6 (2.1)	N.A.	1.930 (0.727, 5.127)	0.1792

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
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Anhang 4-G-1.3.2.2: Häufige schwere UE auf SOC/PT-Ebene

Table 24.2
Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

System Organ Class (%) Preferred Term (%)	Nivolumab + SOC N	Nivolumab + SOC Subjects with Event n (%)	Nivolumab + SOC KME (95%CI) (mon) (1)	SOC N	SOC Subjects with Event n (%)	SOC KME (95%CI) (mon) (1)	Nivolumab + SOC vs. SOC HR (95%CI) (2)	Nivolumab + SOC vs. SOC P-value (3)
TOTAL SUBJECTS WITH AN EVENT	304	246 (80.9)	1.91 (1.51, 2.30)	288	206 (71.5)	2.33 (1.81, 2.99)	1.157 (0.958, 1.397)	0.1339
BLOOD AND LYMPHATIC SYSTEM DISORDERS	304	125 (41.1)	N.A.	288	111 (38.5)	11.50 (N.A., N.A.)	1.030 (0.796, 1.331)	0.8234
ANAEMIA	304	79 (26.0)	N.A.	288	65 (22.6)	11.50 (11.50, N.A.)	1.099 (0.789, 1.530)	0.5796
NEUTROPENIA	304	61 (20.1)	N.A.	288	44 (15.3)	N.A.	1.299 (0.882, 1.915)	0.1841
THROMBOCYTOPENIA	304	26 (8.6)	N.A.	288	15 (5.2)	N.A.	1.492 (0.782, 2.846)	0.2213
INVESTIGATIONS	304	88 (28.9)	N.A.	288	60 (20.8)	N.A.	1.359 (0.976, 1.893)	0.0690
NEUTROPHIL COUNT DECREASED	304	46 (15.1)	N.A.	288	33 (11.5)	N.A.	1.347 (0.861, 2.107)	0.1906
WHITE BLOOD CELL COUNT DECREASED	304	31 (10.2)	N.A.	288	11 (3.8)	N.A.	2.771 (1.393, 5.514)	0.0025*
PLATELET COUNT DECREASED	304	27 (8.9)	N.A.	288	16 (5.6)	12.65 (12.65, N.A.)	1.509 (0.807, 2.821)	0.1947

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-taesocpthrta-ebr2114-b2.sas 15MAR2024:12:37:50

Table 24.2
Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

System Organ Class (%) Preferred Term (%)	Nivolumab + SOC N	Nivolumab + SOC Subjects with Event n (%)	Nivolumab + SOC KME (95%CI) (mon) (1)	SOC N	SOC Subjects with Event n (%)	SOC KME (95%CI) (mon) (1)	Nivolumab + SOC vs. SOC HR (95%CI) (2)	Nivolumab + SOC vs. SOC P-value (3)
LIPASE INCREASED	304	10 (3.3)	N.A.	288	4 (1.4)	N.A.	1.803 (0.542, 6.002)	0.3298
INFECTIONS AND INFESTATIONS	304	57 (18.8)	N.A.	288	48 (16.7)	N.A.	0.818 (0.544, 1.229)	0.3330
URINARY TRACT INFECTION	304	18 (5.9)	N.A.	288	15 (5.2)	N.A.	0.858 (0.417, 1.765)	0.6768
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	304	52 (17.1)	N.A.	288	26 (9.0)	N.A.	1.013 (0.606, 1.694)	0.9599
MALIGNANT NEOPLASM PROGRESSION	304	46 (15.1)	N.A.	288	23 (8.0)	N.A.	1.032 (0.598, 1.781)	0.9091
METABOLISM AND NUTRITION DISORDERS	304	46 (15.1)	N.A.	288	30 (10.4)	N.A.	1.229 (0.764, 1.977)	0.3944
HYPONATRAEMIA	304	16 (5.3)	N.A.	288	9 (3.1)	N.A.	1.475 (0.641, 3.394)	0.3573
GASTROINTESTINAL DISORDERS	304	35 (11.5)	N.A.	288	20 (6.9)	N.A.	1.168 (0.653, 2.089)	0.6025
RENAL AND URINARY DISORDERS	304	32 (10.5)	N.A.	288	20 (6.9)	N.A.	1.207 (0.676, 2.154)	0.5240

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-taesocpthrta-ebr2114-b2.sas 15MAR2024:12:37:50

Table 24.2
Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
ACUTE KIDNEY INJURY	304	16 (5.3)	N.A.	288	6 (2.1)	N.A.	2.082 (0.796, 5.444)	0.1265
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	304	31 (10.2)	N.A.	288	22 (7.6)	N.A.	1.057 (0.600, 1.862)	0.8444
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	304	26 (8.6)	N.A.	288	12 (4.2)	N.A.	1.802 (0.894, 3.630)	0.0944
PULMONARY EMBOLISM	304	11 (3.6)	N.A.	288	8 (2.8)	N.A.	1.218 (0.484, 3.063)	0.6742
VASCULAR DISORDERS	304	23 (7.6)	N.A.	288	11 (3.8)	N.A.	1.369 (0.638, 2.935)	0.4180
NERVOUS SYSTEM DISORDERS	304	14 (4.6)	N.A.	288	7 (2.4)	N.A.	1.076 (0.403, 2.874)	0.8825
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	304	12 (3.9)	N.A.	288	6 (2.1)	N.A.	1.039 (0.355, 3.038)	0.9441

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-taesocpthrta-ebr2114-b2.sas 15MAR2024:12:37:50

Anhang 4-G-1.3.2.3: Häufige schwerwiegende UE auf SOC/PT-Ebene

Protocol: CA209901

Table 24.3
Serious Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	304	168 (55.3)	9.76 (7.85, 17.25)	288	127 (44.1)	8.71 (7.10, N.A.)	0.944 (0.741, 1.203)	0.6391
INFECTIONS AND INFESTATIONS	304	58 (19.1)	N.A.	288	45 (15.6)	N.A.	0.888 (0.588, 1.342)	0.5752
URINARY TRACT INFECTION	304	15 (4.9)	N.A.	288	16 (5.6)	N.A.	0.689 (0.329, 1.443)	0.3213
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	304	54 (17.8)	N.A.	288	24 (8.3)	N.A.	1.187 (0.708, 1.992)	0.5146
MALIGNANT NEOPLASM PROGRESSION	304	47 (15.5)	N.A.	288	21 (7.3)	N.A.	1.194 (0.686, 2.076)	0.5300
GASTROINTESTINAL DISORDERS	304	30 (9.9)	N.A.	288	17 (5.9)	N.A.	1.154 (0.614, 2.170)	0.6572
RENAL AND URINARY DISORDERS	304	27 (8.9)	N.A.	288	20 (6.9)	N.A.	0.951 (0.517, 1.749)	0.8724
ACUTE KIDNEY INJURY	304	13 (4.3)	N.A.	288	5 (1.7)	N.A.	2.047 (0.713, 5.879)	0.1742
BLOOD AND LYMPHATIC SYSTEM DISORDERS	304	20 (6.6)	N.A.	288	14 (4.9)	N.A.	1.112 (0.548, 2.255)	0.7696

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-taesocpthrta-ebr2114-b2.sas 15MAR2024:12:37:52

Protocol: CA209901

Table 24.3
Serious Adverse Events: Time-Adjusted Analyses
by SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
System Organ Class (%) Preferred Term (%)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	HR (95%CI) (2)	P-value (3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	304	18 (5.9)	N.A.	288	17 (5.9)	N.A.	0.620 (0.300, 1.285)	0.1952
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	304	17 (5.6)	N.A.	288	10 (3.5)	N.A.	1.267 (0.560, 2.864)	0.5689
METABOLISM AND NUTRITION DISORDERS	304	12 (3.9)	N.A.	288	9 (3.1)	N.A.	0.797 (0.311, 2.043)	0.6357
NERVOUS SYSTEM DISORDERS	304	12 (3.9)	N.A.	288	5 (1.7)	N.A.	1.505 (0.500, 4.531)	0.4640
INVESTIGATIONS	304	10 (3.3)	N.A.	288	5 (1.7)	N.A.	1.696 (0.569, 5.059)	0.3378
VASCULAR DISORDERS	304	10 (3.3)	N.A.	288	4 (1.4)	N.A.	2.126 (0.658, 6.867)	0.1969

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Log-rank test stratified by PDL1 status and liver metastasis at Study Entry, as entered in IRT.
(4) P-values <0.05 are indicated by 1 asterisk.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-taesocpthrta-ebr2114-b2.sas 15MAR2024:12:37:52

Anhang 4-G-1.3.2.4: Zum Therapieabbruch führende UE auf SOC/PT-Ebene

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Table 28.1
Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects - Arm C and D

System Organ Class (%) Preferred Term (%)	Nivolumab + SOC N = 304			SOC N = 288		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	99 (32.6)	57 (18.8)	3 (1.0)	72 (25.0)	39 (13.5)	2 (0.7)
Renal and urinary disorders	18 (5.9)	7 (2.3)	0	11 (3.8)	4 (1.4)	0
Acute kidney injury	9 (3.0)	6 (2.0)	0	6 (2.1)	2 (0.7)	0
Renal impairment	4 (1.3)	0	0	1 (0.3)	0	0
Renal failure	3 (1.0)	1 (0.3)	0	3 (1.0)	1 (0.3)	0
Haematuria	1 (0.3)	0	0	0	0	0
Pollakiuria	1 (0.3)	0	0	0	0	0
Urinary incontinence	1 (0.3)	0	0	0	0	0
Chronic kidney disease	0	0	0	1 (0.3)	1 (0.3)	0
Investigations	16 (5.3)	3 (1.0)	0	15 (5.2)	3 (1.0)	0
Blood creatinine increased	9 (3.0)	0	0	7 (2.4)	0	0
Glomerular filtration rate decreased	2 (0.7)	0	0	2 (0.7)	0	0
Alanine aminotransferase increased	1 (0.3)	1 (0.3)	0	0	0	0
Blood bilirubin increased	1 (0.3)	1 (0.3)	0	0	0	0
Neutrophil count decreased	1 (0.3)	0	0	2 (0.7)	2 (0.7)	0
Pancreatic enzymes decreased	1 (0.3)	0	0	0	0	0
Platelet count decreased	1 (0.3)	1 (0.3)	0	6 (2.1)	1 (0.3)	0
White blood cell count decreased	1 (0.3)	0	0	2 (0.7)	2 (0.7)	0
Aspartate aminotransferase increased	0	0	0	1 (0.3)	1 (0.3)	0
Blood lactate dehydrogenase increased	0	0	0	1 (0.3)	0	0
Blood urea increased	0	0	0	1 (0.3)	0	0
Gamma-glutamyltransferase increased	0	0	0	1 (0.3)	0	0

June 2023 DBL Includes events reported from the first dose of study therapy
MedDRA Version: 26.0; CTC Version 4
Includes events reported between first dose and 100 days after last dose of study treatment.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-aecat-ebr2114-b3.sas 12APR2024:08:21:57

Protocol: CA209901

Table 28.1
Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects - Arm C and D

	Nivolumab + SOC N = 304			SOC N = 288		
System Organ Class (%) Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Blood and lymphatic system disorders	12 (3.9)	12 (3.9)	0	17 (5.9)	10 (3.5)	0
Thrombocytopenia	6 (2.0)	5 (1.6)	0	2 (0.7)	1 (0.3)	0
Anaemia	4 (1.3)	3 (1.0)	0	8 (2.8)	4 (1.4)	0
Febrile neutropenia	4 (1.3)	4 (1.3)	0	0	0	0
Neutropenia	4 (1.3)	3 (1.0)	0	6 (2.1)	4 (1.4)	0
Leukopenia	1 (0.3)	1 (0.3)	0	0	0	0
Lymphopenia	1 (0.3)	0	0	0	0	0
Myelosuppression	1 (0.3)	1 (0.3)	0	1 (0.3)	1 (0.3)	0
Infections and infestations	11 (3.6)	8 (2.6)	2 (0.7)	9 (3.1)	7 (2.4)	0
Sepsis	4 (1.3)	2 (0.7)	2 (0.7)	1 (0.3)	1 (0.3)	0
Septic shock	2 (0.7)	2 (0.7)	0	1 (0.3)	1 (0.3)	0
Herpes zoster meningoencephalitis	1 (0.3)	1 (0.3)	0	0	0	0
Klebsiella sepsis	1 (0.3)	1 (0.3)	0	0	0	0
Meningitis	1 (0.3)	1 (0.3)	0	0	0	0
Pulpitis dental	1 (0.3)	0	0	0	0	0
Urinary tract infection	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0
COVID-19	0	0	0	2 (0.7)	2 (0.7)	0
Fungal infection	0	0	0	1 (0.3)	1 (0.3)	0
Peritonitis	0	0	0	1 (0.3)	1 (0.3)	0
Respiratory tract infection	0	0	0	1 (0.3)	0	0
Systemic infection	0	0	0	1 (0.3)	1 (0.3)	0
Gastrointestinal disorders	10 (3.3)	9 (3.0)	0	6 (2.1)	3 (1.0)	0
Intestinal obstruction	3 (1.0)	3 (1.0)	0	0	0	0
Ascites	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0
Autoimmune enteropathy	1 (0.3)	1 (0.3)	0	0	0	0
Diarrhoea	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0

June 2023 DBL Includes events reported from the first dose of study therapy
MedDRA Version: 26.0; CTC Version 4
Includes events reported between first dose and 100 days after last dose of study treatment.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-aecat-ebr2114-b3.sas 12APR2024:08:21:57

Table 28.1
Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects - Arm C and D

	Nivolumab + SOC N = 304			SOC N = 288		
System Organ Class (%) Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Gastric ulcer perforation	1 (0.3)	1 (0.3)	0	0	0	0
Pancreatitis	1 (0.3)	0	0	0	0	0
Rectal lesion	1 (0.3)	1 (0.3)	0	0	0	0
Small intestinal obstruction	1 (0.3)	1 (0.3)	0	0	0	0
Dysphagia	0	0	0	1 (0.3)	1 (0.3)	0
Gastric perforation	0	0	0	1 (0.3)	1 (0.3)	0
Large intestine perforation	0	0	0	1 (0.3)	1 (0.3)	0
Nausea	0	0	0	2 (0.7)	0	0
Vomiting	0	0	0	2 (0.7)	0	0
General disorders and administration site conditions	9 (3.0)	4 (1.3)	0	8 (2.8)	2 (0.7)	1 (0.3)
Fatigue	6 (2.0)	3 (1.0)	0	1 (0.3)	0	0
Asthenia	2 (0.7)	0	0	2 (0.7)	1 (0.3)	0
General physical health deterioration	1 (0.3)	1 (0.3)	0	1 (0.3)	1 (0.3)	0
Disease progression	0	0	0	1 (0.3)	0	1 (0.3)
Malaise	0	0	0	2 (0.7)	0	0
Pyrexia	0	0	0	1 (0.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (2.3)	6 (2.0)	0	5 (1.7)	5 (1.7)	0
Malignant neoplasm progression	7 (2.3)	6 (2.0)	0	5 (1.7)	5 (1.7)	0
Nervous system disorders	7 (2.3)	5 (1.6)	0	3 (1.0)	2 (0.7)	0
Neuropathy peripheral	2 (0.7)	1 (0.3)	0	0	0	0
Peripheral sensory neuropathy	2 (0.7)	2 (0.7)	0	0	0	0
Cerebral ischaemia	1 (0.3)	1 (0.3)	0	0	0	0

June 2023 DBL Includes events reported from the first dose of study therapy
MedDRA Version: 26.0; CTC Version 4
Includes events reported between first dose and 100 days after last dose of study treatment.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-aecat-ebr2114-b3.sas 12APR2024:08:21:57

Protocol: CA209901

Table 28.1
Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects - Arm C and D

	Nivolumab + SOC N = 304			SOC N = 288		
System Organ Class (%) Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Embolic stroke	1 (0.3)	0	0	0	0	0
Encephalitis autoimmune	1 (0.3)	1 (0.3)	0	0	0	0
Headache	1 (0.3)	0	0	1 (0.3)	0	0
Syncope	1 (0.3)	1 (0.3)	0	0	0	0
Depressed level of consciousness	0	0	0	1 (0.3)	1 (0.3)	0
Dizziness	0	0	0	2 (0.7)	1 (0.3)	0
Thrombotic stroke	0	0	0	1 (0.3)	1 (0.3)	0
Ear and labyrinth disorders	6 (2.0)	0	0	8 (2.8)	1 (0.3)	0
Tinnitus	4 (1.3)	0	0	4 (1.4)	0	0
Deafness	1 (0.3)	0	0	2 (0.7)	0	0
Hypoacusis	1 (0.3)	0	0	2 (0.7)	1 (0.3)	0
Ear pain	0	0	0	1 (0.3)	0	0
Endocrine disorders	5 (1.6)	1 (0.3)	0	0	0	0
Adrenal insufficiency	2 (0.7)	1 (0.3)	0	0	0	0
Hypothyroidism	2 (0.7)	0	0	0	0	0
Hyperthyroidism	1 (0.3)	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	5 (1.6)	3 (1.0)	0	2 (0.7)	2 (0.7)	0
Immune-mediated lung disease	1 (0.3)	1 (0.3)	0	0	0	0
Interstitial lung disease	1 (0.3)	0	0	0	0	0
Pulmonary embolism	1 (0.3)	1 (0.3)	0	2 (0.7)	2 (0.7)	0
Pulmonary toxicity	1 (0.3)	0	0	0	0	0
Respiratory failure	1 (0.3)	1 (0.3)	0	0	0	0
Cardiac disorders	4 (1.3)	3 (1.0)	0	2 (0.7)	0	1 (0.3)
Angina pectoris	1 (0.3)	1 (0.3)	0	0	0	0
Cardiac failure	1 (0.3)	0	0	0	0	0

June 2023 DBL Includes events reported from the first dose of study therapy
MedDRA Version: 26.0; CTC Version 4
Includes events reported between first dose and 100 days after last dose of study treatment.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-aecat-ebr2114-b3.sas 12APR2024:08:21:57

Table 28.1
Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects - Arm C and D

	Nivolumab + SOC N = 304			SOC N = 288		
System Organ Class (%) Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Immune-mediated myocarditis	1 (0.3)	1 (0.3)	0	0	0	0
Myocarditis	1 (0.3)	1 (0.3)	0	0	0	0
Cardio-respiratory arrest	0	0	0	1 (0.3)	0	1 (0.3)
Palpitations	0	0	0	1 (0.3)	0	0
Vascular disorders	4 (1.3)	3 (1.0)	1 (0.3)	1 (0.3)	1 (0.3)	0
Hypovolaemic shock	2 (0.7)	1 (0.3)	1 (0.3)	0	0	0
Deep vein thrombosis	1 (0.3)	1 (0.3)	0	0	0	0
Hypertension	1 (0.3)	1 (0.3)	0	0	0	0
Thrombosis	0	0	0	1 (0.3)	1 (0.3)	0
Metabolism and nutrition disorders	3 (1.0)	1 (0.3)	0	7 (2.4)	5 (1.7)	0
Decreased appetite	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0
Hypoalbuminaemia	1 (0.3)	0	0	0	0	0
Hypomagnesaemia	1 (0.3)	0	0	2 (0.7)	1 (0.3)	0
Cachexia	0	0	0	1 (0.3)	1 (0.3)	0
Hyperglycaemia	0	0	0	1 (0.3)	1 (0.3)	0
Hyperkalaemia	0	0	0	1 (0.3)	0	0
Hypernatraemia	0	0	0	1 (0.3)	0	0
Hypokalaemia	0	0	0	1 (0.3)	1 (0.3)	0
Hyponatraemia	0	0	0	1 (0.3)	1 (0.3)	0
Musculoskeletal and connective tissue disorders	3 (1.0)	1 (0.3)	0	2 (0.7)	0	0
Hypercreatinaemia	1 (0.3)	0	0	1 (0.3)	0	0
Myalgia	1 (0.3)	1 (0.3)	0	0	0	0
Rheumatoid arthritis	1 (0.3)	0	0	0	0	0
Back pain	0	0	0	1 (0.3)	0	0
Osteoporosis	0	0	0	1 (0.3)	0	0

June 2023 DBL Includes events reported from the first dose of study therapy
MedDRA Version: 26.0; CTC Version 4
Includes events reported between first dose and 100 days after last dose of study treatment.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-aecat-ebr2114-b3.sas 12APR2024:08:21:57

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Table 28.1
Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects - Arm C and D

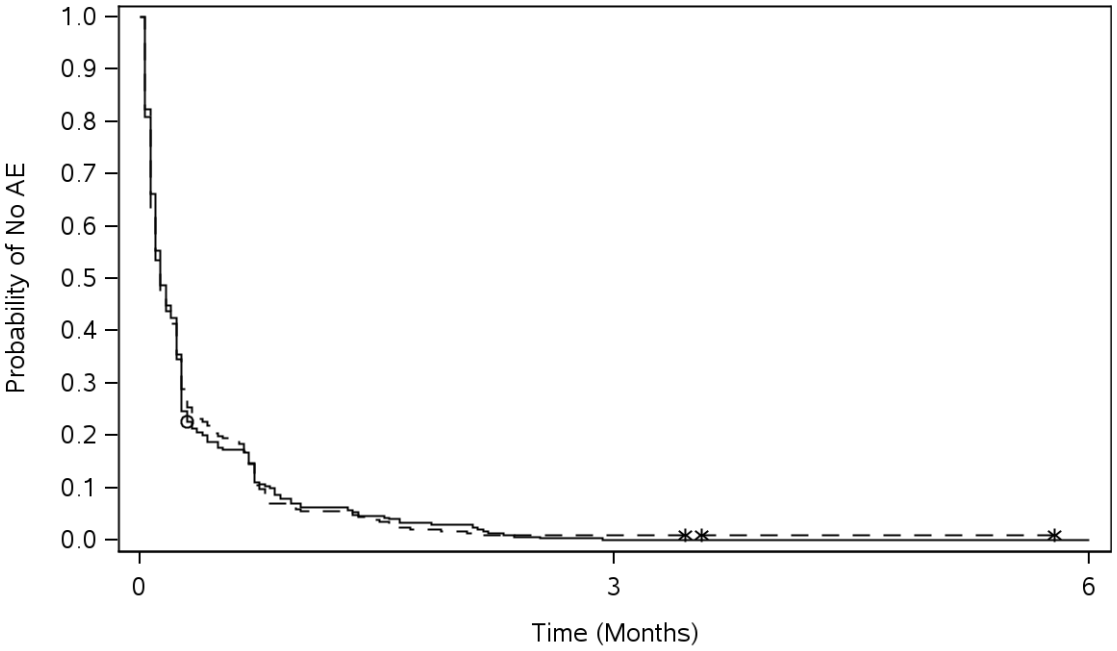
	Nivolumab + SOC N = 304			SOC N = 288		
System Organ Class (%) Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Eye disorders	1 (0.3)	0	0	0	0	0
Optic ischaemic neuropathy	1 (0.3)	0	0	0	0	0
Immune system disorders	1 (0.3)	1 (0.3)	0	0	0	0
Drug hypersensitivity	1 (0.3)	1 (0.3)	0	0	0	0
Injury, poisoning and procedural complications	1 (0.3)	1 (0.3)	0	0	0	0
Spinal compression fracture	1 (0.3)	1 (0.3)	0	0	0	0
Psychiatric disorders	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0
Confusional state	1 (0.3)	1 (0.3)	0	0	0	0
Depression	0	0	0	1 (0.3)	0	0
Skin and subcutaneous tissue disorders	1 (0.3)	1 (0.3)	0	0	0	0
Rash maculo-papular	1 (0.3)	1 (0.3)	0	0	0	0
Hepatobiliary disorders	0	0	0	1 (0.3)	1 (0.3)	0
Hepatic cirrhosis	0	0	0	1 (0.3)	1 (0.3)	0

June 2023 DBL Includes events reported from the first dose of study therapy
MedDRA Version: 26.0; CTC Version 4
Includes events reported between first dose and 100 days after last dose of study treatment.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-aecat-ebr2114-b3.sas 12APR2024:08:21:57

Anhang 4-G-1.3.3: Kaplan-Meier-Kurven zu den Endpunkten zur Verträglichkeit

Anhang 4-G-1.3.3.1: Jegliche UE (Kaplan-Meier-Kurve)

Figure 5.1
Kaplan-Meier Plot of Time to any Adverse Events - Excluding Progression Terms - All Treated Subjects - Arm C and D



Number of Subjects at Risk

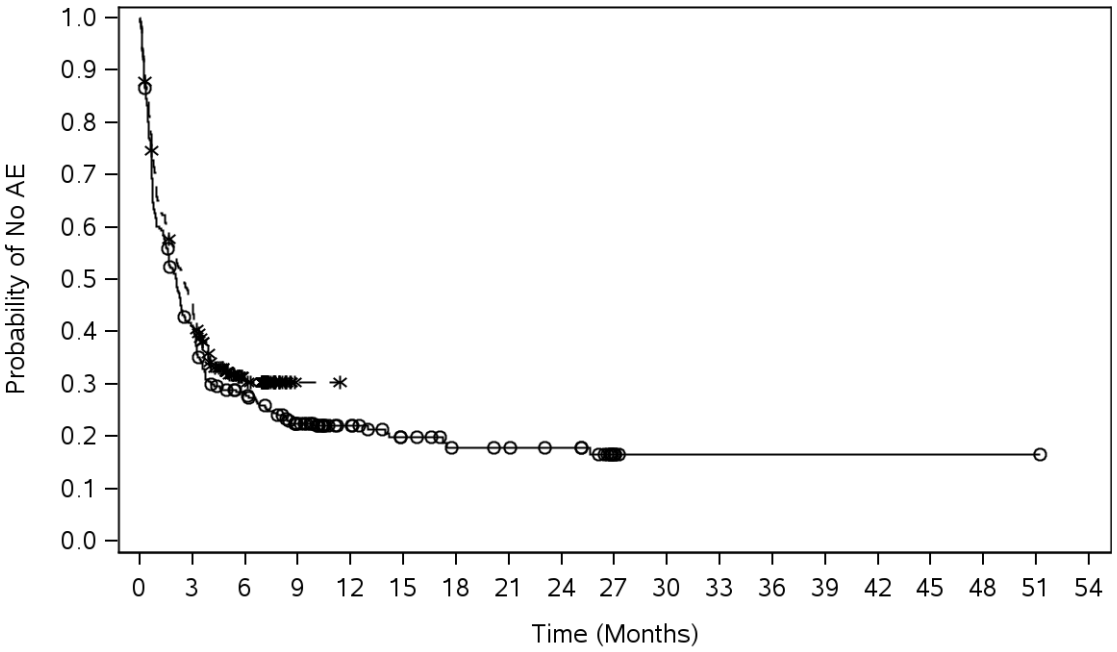
Nivolumab + SOC			
	304	0	0
SOC			
	288	3	0

Nivolumab + SOC (events: 303/304), median and 95% CI: 0.13 (0.10, 0.16)
SOC (events: 285/288), median and 95% CI: 0.13 (0.10, 0.20)
Hazard Ratio (Nivolumab + SOC vs. SOC) and 95% CI: 0.995 (0.845, 1.172)

June 2023 DBL Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
Stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/figures
Program Name: rg-ae-ae-ebr2114.sas 01MAR2024:02:54:30

Anhang 4-G-1.3.3.2: Schwere UE (Kaplan-Meier-Kurve)

Figure 5.2
Kaplan-Meier Plot of Time to any Adverse Events with CTCAE Grade 3-4-5 - Excluding Progression Terms - All Treated Subjects - Arm C and D



Number of Subjects at Risk

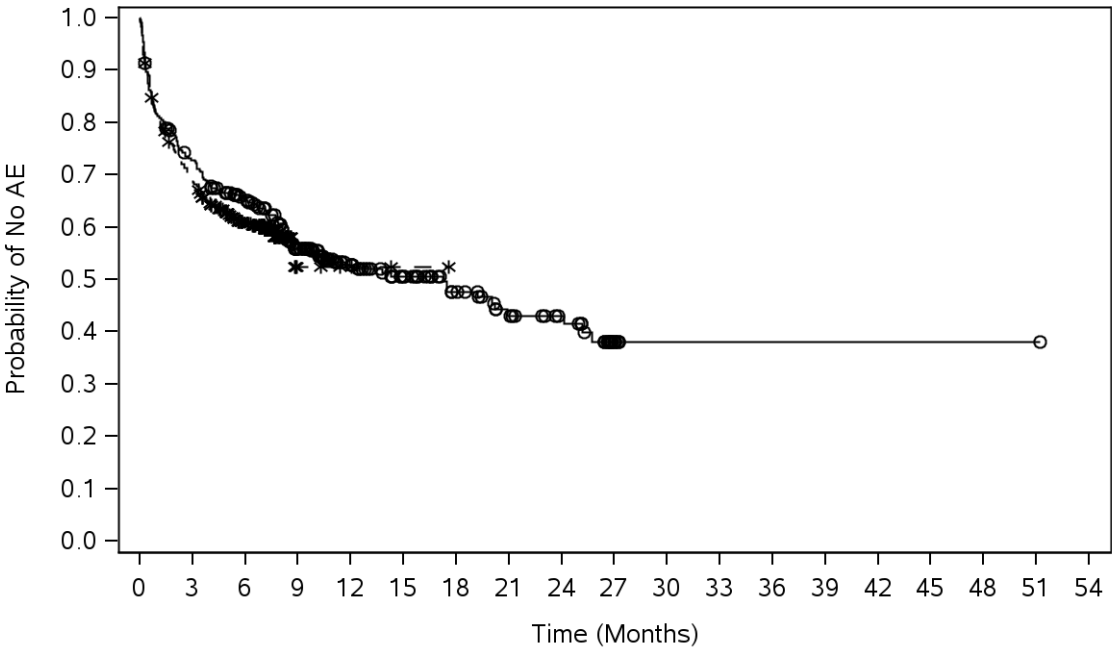
Nivolumab + SOC	304	122	78	52	34	24	18	17	15	4	1	1	1	1	1	1	1	1	0
SOC	288	127	57	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Nivolumab + SOC (events: 238/304), median and 95% CI: 2.07 (1.61, 2.33)
SOC (events: 196/288), median and 95% CI: 2.43 (1.91, 3.02)
Hazard Ratio (Nivolumab + SOC vs. SOC) and 95% CI: 1.178 (0.972, 1.428)

June 2023 DBL Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
Stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/figures
Program Name: rg-ae-ae-ebr2114.sas 01MAR2024:02:54:47

Anhang 4-G-1.3.3.3: Schwerwiegende UE (Kaplan-Meier-Kurve)

Figure 5.3
Kaplan-Meier Plot of Time to any Serious Adverse Events - Excluding Progression Terms - All Treated Subjects - Arm C and D



Number of Subjects at Risk

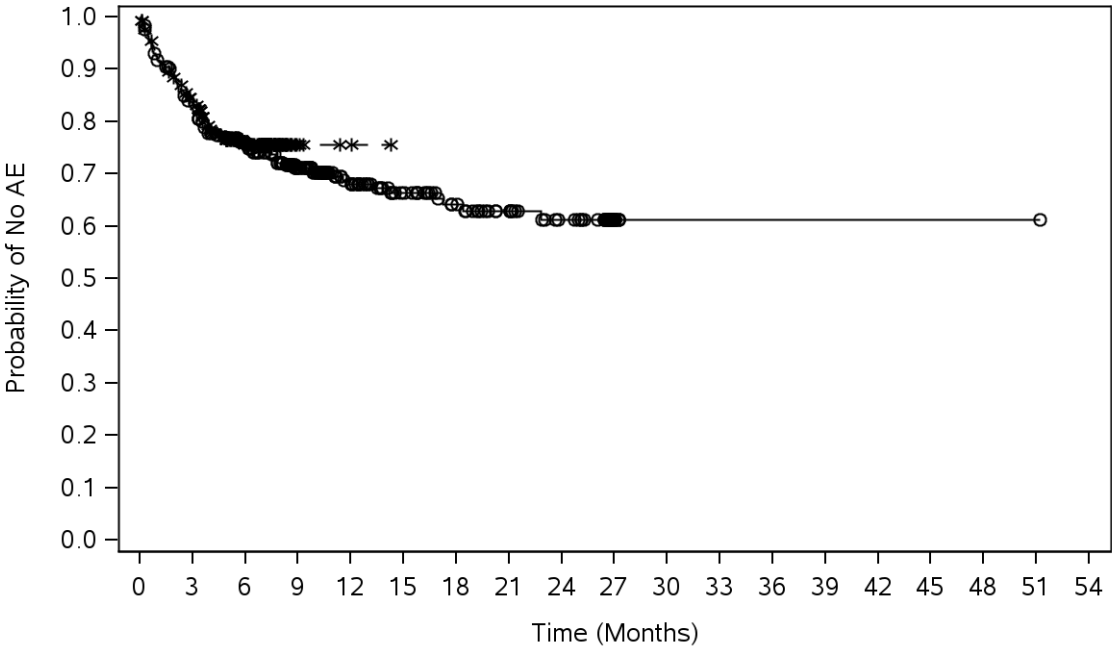
Nivolumab + SOC	304	217	180	127	84	63	47	35	28	7	1	1	1	1	1	1	1	0
SOC	288	196	138	5	3	1	0	0	0	0	0	0	0	0	0	0	0	0

—o— Nivolumab + SOC (events: 147/304), median and 95% CI: 17.25 (8.80, 24.15)
—*· SOC (events: 115/288), median and 95% CI: N.A. (8.71, N.A.)
Hazard Ratio (Nivolumab + SOC vs. SOC) and 95% CI: 0.913 (0.706, 1.180)

June 2023 DBL Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
Stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/figures
Program Name: rg-ae-ae-ebr2114.sas 01MAR2024:02:55:02

Anhang 4-G-1.3.3.4: Zum Therapieabbruch führende UE (Kaplan-Meier-Kurve)

Figure 5.4
Kaplan-Meier Plot of Time to any Adverse Events Leading to Discontinuation of Study Treatment - Excluding Progression Terms - All Treated Subjects - Arm C and D



Number of Subjects at Risk

Nivolumab + SOC	304	242	203	149	97	69	54	42	31	7	1	1	1	1	1	1	1	0
SOC	288	232	157	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0

—o— Nivolumab + SOC (events: 94/304), median and 95% CI: N.A.
—*· SOC (events: 67/288), median and 95% CI: N.A.
Hazard Ratio (Nivolumab + SOC vs. SOC) and 95% CI: 1.091 (0.788, 1.510)

June 2023 DBL Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
Stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/figures
Program Name: rg-ae-ae-ebr2114.sas 01MAR2024:02:55:16

Anhang 4-G-1.4: Subgruppenanalysen

Anhang 4-G-1.4.1: Subgruppenanalysen – In Modul 4 dargestellte Endpunkte

Anhang 4-G-1.4.1.1: Subgruppenanalysen für den Endpunkt zur Mortalität – Gesamtüberleben

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Table 8.1
Subgroup Analyses of Overall Survival
All Randomized Subjects - Arm C and D

Subgroup	Nivolumab+SOC N	Nivolumab+SOC Subjects with event n (%)	Nivolumab+SOC KME (95% CI)(mon) (1)	SOC N	SOC Subjects with event n (%)	SOC KME (95% CI)(mon) (1)	Nivolumab+SOC vs. SOC HR (95% CI) p-value (2)(3)	Test for interaction p-value (4)(5)
OVERALL	304	172 (56.6)	21.72 (18.63, 26.38)	304	193 (63.5)	18.86 (14.72, 22.44)	0.777 (0.632, 0.954) 0.0157	
PD-L1 STATUS								0.5790
>= 1%	112	64 (57.1)	25.10 (17.28, 35.55)	109	66 (60.6)	15.34 (11.70, 24.87)	0.738 (0.523, 1.042) 0.0837	
< 1%	192	108 (56.3)	21.06 (17.54, 26.71)	195	127 (65.1)	20.76 (16.07, 23.26)	0.815 (0.631, 1.054) 0.1170	
AGE CATEGORIZATION								0.5429
< 65	150	85 (56.7)	23.43 (17.97, 31.93)	148	100 (67.6)	17.58 (13.34, 21.78)	0.688 (0.515, 0.920) 0.0110	
>= 65 AND < 75	120	65 (54.2)	21.72 (15.21, 36.44)	116	66 (56.9)	21.68 (14.72, 28.19)	0.891 (0.632, 1.255) 0.5095	
>= 75	34	22 (64.7)	18.04 (10.94, 21.16)	40	27 (67.5)	13.34 (7.89, 26.12)	0.859 (0.485, 1.521) 0.6052	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ef-ossub-ebr2114.sas 29FEB2024:10:32:13

Table 8.1
Subgroup Analyses of Overall Survival
All Randomized Subjects - Arm C and D

Subgroup	Nivolumab+SOC N	Nivolumab+SOC Subjects with event n (%)	Nivolumab+SOC KME (95% CI)(mon) (1)	SOC N	SOC Subjects with event n (%)	SOC KME (95% CI)(mon) (1)	Nivolumab+SOC vs. SOC HR (95% CI) p-value (2)(3)	Test for interaction p-value (4)(5)
SEX								0.7946
FEMALE	68	39 (57.4)	21.09 (14.39, 46.29)	70	46 (65.7)	18.86 (13.86, 24.87)	0.824 (0.537, 1.263) 0.3711	
MALE	236	133 (56.4)	23.13 (18.99, 27.47)	234	147 (62.8)	19.45 (14.13, 23.26)	0.764 (0.604, 0.966) 0.0240	
RACE								0.9104
WHITE	211	123 (58.3)	21.09 (16.30, 27.24)	225	145 (64.4)	20.21 (14.32, 23.46)	0.802 (0.630, 1.020) 0.0708	
ASIAN	75	38 (50.7)	26.02 (18.99, 28.91)	63	36 (57.1)	16.30 (11.76, 24.44)	0.707 (0.447, 1.118) 0.1360	
OTHER	17	11 (64.7)	19.35 (10.15, N.A.)	13	10 (76.9)	17.58 (10.61, 25.95)	0.830 (0.352, 1.959) 0.6705	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ef-ossub-ebr2114.sas 29FEB2024:10:32:13

Table 8.1
Subgroup Analyses of Overall Survival
All Randomized Subjects - Arm C and D

Subgroup	Nivolumab+SOC N	Nivolumab+SOC Subjects with event n (%)	Nivolumab+SOC KME (95% CI)(mon) (1)	SOC N	SOC Subjects with event n (%)	SOC KME (95% CI)(mon) (1)	Nivolumab+SOC vs. SOC HR (95% CI) p-value (2)(3)	Test for interaction p-value (4)(5)
REGION								0.0688
US	19	18 (94.7)	11.99 (6.08, 21.72)	21	15 (71.4)	19.61 (11.70, 36.93)	1.923 (0.953, 3.880) 0.0621	
ASIA	72	36 (50.0)	24.02 (18.99, 28.91)	61	34 (55.7)	18.86 (11.99, 24.87)	0.731 (0.457, 1.170) 0.1903	
EUROPE	134	72 (53.7)	25.10 (17.94, 46.29)	142	90 (63.4)	20.76 (14.29, 25.49)	0.725 (0.532, 0.990) 0.0418	
REST OF THE WORLD	79	46 (58.2)	20.11 (14.39, 37.45)	80	54 (67.5)	14.72 (10.91, 20.80)	0.726 (0.489, 1.078) 0.1102	
BASELINE ECOG PERFORMANCE STATUS								0.4295
0	162	74 (45.7)	36.44 (26.18, 47.61)	162	87 (53.7)	25.95 (21.16, 30.29)	0.697 (0.511, 0.951) 0.0222	
1	140	96 (68.6)	14.39 (10.68, 17.97)	142	106 (74.6)	12.39 (9.23, 16.30)	0.845 (0.641, 1.114) 0.2320	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ef-ossub-ebr2114.sas 29FEB2024:10:32:13

Table 8.1
Subgroup Analyses of Overall Survival
All Randomized Subjects - Arm C and D

Subgroup	Nivolumab+SOC N	Nivolumab+SOC Subjects with event n (%)	Nivolumab+SOC KME (95% CI)(mon) (1)	SOC N	SOC Subjects with event n (%)	SOC KME (95% CI)(mon) (1)	Nivolumab+SOC vs. SOC HR (95% CI) p-value (2)(3)	Test for interaction p-value (4)(5)
LIVER METASTASIS								0.8489
YES	62	45 (72.6)	10.15 (8.08, 18.04)	62	46 (74.2)	8.94 (5.75, 11.66)	0.838 (0.553, 1.269) 0.4021	
NO	242	127 (52.5)	26.02 (21.06, 35.55)	242	147 (60.7)	21.78 (17.28, 24.87)	0.753 (0.594, 0.955) 0.0191	
DISEASE STAGE AT STUDY ENTRY								0.7019
STAGE III	37	17 (45.9)	27.47 (16.30, N.A.)	28	13 (46.4)	18.04 (8.61, N.A.)	0.681 (0.330, 1.406) 0.2963	
STAGE IV	265	154 (58.1)	21.06 (17.97, 26.02)	274	179 (65.3)	19.61 (14.72, 22.44)	0.792 (0.638, 0.982) 0.0334	
PRIOR RADIOTHERAPY								0.4954
YES	26	18 (69.2)	12.45 (8.54, 16.10)	24	20 (83.3)	16.30 (7.56, 20.34)	1.004 (0.525, 1.919) 0.9861	
NO	278	154 (55.4)	23.43 (20.11, 27.73)	280	173 (61.8)	19.98 (14.72, 23.26)	0.764 (0.615, 0.950) 0.0151	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ef-ossub-ebr2114.sas 29FEB2024:10:32:13

Protocol: CA209901 Page 5 of 5

Table 8.1
Subgroup Analyses of Overall Survival
All Randomized Subjects - Arm C and D

Subgroup	Nivolumab+SOC N	Nivolumab+SOC Subjects with event n (%)	Nivolumab+SOC KME (95% CI)(mon) (1)	SOC N	SOC Subjects with event n (%)	SOC KME (95% CI)(mon) (1)	Nivolumab+SOC vs. SOC HR (95% CI) p-value (2)(3)	Test for interaction p-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.5592
YES	88	44 (50.0)	25.10 (17.54, 33.84)	68	41 (60.3)	23.79 (19.75, 29.60)	0.902 (0.588, 1.383) 0.6382	
NO	216	128 (59.3)	21.09 (17.94, 27.47)	236	152 (64.4)	16.07 (13.34, 20.76)	0.760 (0.600, 0.962) 0.0220	
PD-L1 STATUS (IRT)								0.7091
>=1%	111	64 (57.7)	25.10 (17.28, 35.55)	110	67 (60.9)	15.34 (11.70, 24.87)	0.752 (0.534, 1.061) 0.1038	
<1%/INDETERMINATE	193	108 (56.0)	21.06 (17.54, 26.71)	194	126 (64.9)	20.76 (16.07, 23.26)	0.803 (0.621, 1.038) 0.0928	
LIVER METASTASIS (IRT)								0.7605
YES	64	45 (70.3)	11.99 (8.64, 20.04)	64	48 (75.0)	8.94 (5.75, 12.88)	0.768 (0.509, 1.159) 0.2071	
NO	240	127 (52.9)	26.02 (21.06, 35.55)	240	145 (60.4)	22.44 (17.81, 25.49)	0.771 (0.608, 0.979) 0.0324	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ef-ossub-ebr2114.sas 29FEB2024:10:32:13

Anhang 4-G-1.4.1.2: Subgruppenanalysen für die Endpunkte zur Morbidität – Gesundheitszustand gemäß EQ-5D-VAS

Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	273	92 (33.7)	181 (66.3)	23.16 (16.20, N.A.)	247	54 (21.9)	193 (78.1)	N.A.	1.051 (0.737, 1.499) 0.9564	
PD-L1 STATUS										0.6363
>= 1%	100	30 (30.0)	70 (70.0)	N.A. (15.67, N.A.)	79	16 (20.3)	63 (79.7)	N.A. (4.60, N.A.)	0.847 (0.443, 1.620) 0.4130	
< 1%	173	62 (35.8)	111 (64.2)	23.16 (9.82, N.A.)	168	38 (22.6)	130 (77.4)	N.A.	1.186 (0.776, 1.811) 0.5206	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-sy-tfdsub-ebr2114.sas 09APR2024:11:46:29

Protocol: CA209901

Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.1619
< 65	137	40 (29.2)	97 (70.8)	N.A. (15.67, N.A.)	125	27 (21.6)	98 (78.4)	N.A.	0.726 (0.429, 1.228) 0.1859	
>= 65 AND < 75	108	38 (35.2)	70 (64.8)	20.93 (9.82, N.A.)	91	20 (22.0)	71 (78.0)	N.A. (4.60, N.A.)	1.136 (0.639, 2.020) 0.8543	
>= 75	28	14 (50.0)	14 (50.0)	2.40 (2.07, N.A.)	31	7 (22.6)	24 (77.4)	N.A. (3.88, N.A.)	3.107 (1.237, 7.807) 0.0221	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.9939
FEMALE	60	24 (40.0)	36 (60.0)	23.16 (5.22, N.A.)	54	15 (27.8)	39 (72.2)	N.A. (4.60, N.A.)	1.189 (0.612, 2.312) 0.5369	
MALE	213	68 (31.9)	145 (68.1)	N.A. (16.20, N.A.)	193	39 (20.2)	154 (79.8)	N.A.	0.996 (0.654, 1.518) 0.6678	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.7800
WHITE	190	68 (35.8)	122 (64.2)	20.93 (15.67, N.A.)	181	43 (23.8)	138 (76.2)	N.A.	1.115 (0.747, 1.665) 0.8268	
ASIAN	67	19 (28.4)	48 (71.6)	N.A. (8.15, N.A.)	54	10 (18.5)	44 (81.5)	N.A. (4.60, N.A.)	0.807 (0.348, 1.869) 0.5554	
OTHER	15	5 (33.3)	10 (66.7)	N.A. (2.60, N.A.)	10	1 (10.0)	9 (90.0)	N.A. (2.56, N.A.)	1.757 (0.179, 17.282) 0.7489	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.8254
US	16	4 (25.0)	12 (75.0)	N.A. (2.40, N.A.)	17	2 (11.8)	15 (88.2)	N.A.	2.112 (0.383, 11.657) 0.3352	
ASIA	66	19 (28.8)	47 (71.2)	N.A. (8.11, N.A.)	52	10 (19.2)	42 (80.8)	N.A. (4.60, N.A.)	0.824 (0.355, 1.909) 0.5349	
EUROPE	122	41 (33.6)	81 (66.4)	N.A. (16.20, N.A.)	115	24 (20.9)	91 (79.1)	N.A.	1.315 (0.777, 2.226) 0.6059	
REST OF THE WORLD	69	28 (40.6)	41 (59.4)	15.67 (8.54, N.A.)	63	18 (28.6)	45 (71.4)	N.A. (4.21, N.A.)	0.765 (0.403, 1.450) 0.4906	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.0882
0	150	59 (39.3)	91 (60.7)	20.93 (8.11, N.A.)	130	28 (21.5)	102 (78.5)	N.A.	1.411 (0.882, 2.258) 0.2966	
1	121	33 (27.3)	88 (72.7)	23.16 (18.04, N.A.)	117	26 (22.2)	91 (77.8)	N.A.	0.715 (0.412, 1.243) 0.2286	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.6915
YES	56	19 (33.9)	37 (66.1)	11.76 (4.34, N.A.)	47	12 (25.5)	35 (74.5)	N.A. (3.06, N.A.)	1.270 (0.605, 2.668) 0.8401	
NO	217	73 (33.6)	144 (66.4)	23.16 (16.20, N.A.)	200	42 (21.0)	158 (79.0)	N.A.	0.993 (0.661, 1.491) 0.8167	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.0705
STAGE III	34	6 (17.6)	28 (82.4)	N.A.	19	6 (31.6)	13 (68.4)	N.A. (2.30, N.A.)	0.786 (0.242, 2.558) 0.1991	
STAGE IV	237	86 (36.3)	151 (63.7)	20.93 (10.02, N.A.)	227	48 (21.1)	179 (78.9)	N.A.	1.115 (0.768, 1.621) 0.6961	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.4512
YES	22	10 (45.5)	12 (54.5)	4.37 (1.68, N.A.)	18	8 (44.4)	10 (55.6)	2.63 (1.35, N.A.)	0.709 (0.273, 1.841) 0.6211	
NO	251	82 (32.7)	169 (67.3)	23.16 (16.20, N.A.)	229	46 (20.1)	183 (79.9)	N.A.	1.069 (0.728, 1.570) 0.9944	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.4057
YES	79	31 (39.2)	48 (60.8)	18.04 (8.15, N.A.)	53	12 (22.6)	41 (77.4)	N.A. (4.21, N.A.)	1.384 (0.697, 2.747) 0.4012	
NO	194	61 (31.4)	133 (68.6)	23.16 (15.67, N.A.)	194	42 (21.6)	152 (78.4)	N.A.	0.904 (0.592, 1.379) 0.4658	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.7234
>=1%	99	30 (30.3)	69 (69.7)	N.A. (15.67, N.A.)	80	16 (20.0)	64 (80.0)	N.A. (4.60, N.A.)	0.866 (0.453, 1.656) 0.4619	
<1%/ INDETERMINATE	174	62 (35.6)	112 (64.4)	23.16 (10.02, N.A.)	167	38 (22.8)	129 (77.2)	N.A.	1.173 (0.768, 1.792) 0.5647	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.3
Subgroup analyses of Time to First Deterioration EQ-5D-5L VAS
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EQ-5D-VAS (MID = 15)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.5477
YES	58	22 (37.9)	36 (62.1)	11.76 (4.34, N.A.)	49	13 (26.5)	36 (73.5)	N.A. (3.81, N.A.)	1.289 (0.639, 2.601) 0.7234	
NO	215	70 (32.6)	145 (67.4)	23.16 (18.04, N.A.)	198	41 (20.7)	157 (79.3)	N.A.	0.988 (0.654, 1.493) 0.7833	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Anhang 4-G-1.4.1.3: Subgruppenanalysen für die Endpunkte zur Morbidität – Krankheitssymptomatik gemäß EORTC QLQ-C30

Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	193 (69.9)	83 (30.1)	2.20 (2.10, 2.50)	247	139 (56.3)	108 (43.7)	2.76 (2.20, 3.55)	1.117 (0.893, 1.397) 0.6390	
PD-L1 STATUS										0.1215
>= 1%	100	64 (64.0)	36 (36.0)	2.46 (2.10, 5.36)	81	46 (56.8)	35 (43.2)	2.86 (2.04, 3.75)	0.866 (0.585, 1.282) 0.4778	
< 1%	176	129 (73.3)	47 (26.7)	2.14 (1.51, 2.40)	166	93 (56.0)	73 (44.0)	2.56 (2.14, 3.58)	1.280 (0.974, 1.681) 0.2580	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.1837
< 65	139	91 (65.5)	48 (34.5)	2.37 (1.94, 3.55)	124	67 (54.0)	57 (46.0)	2.60 (2.17, 3.81)	1.013 (0.732, 1.402) 0.9729	
>= 65 AND < 75	108	80 (74.1)	28 (25.9)	2.20 (2.10, 3.42)	91	54 (59.3)	37 (40.7)	2.86 (1.87, 3.71)	1.111 (0.779, 1.584) 0.9536	
>= 75	29	22 (75.9)	7 (24.1)	0.95 (0.79, 2.40)	32	18 (56.3)	14 (43.8)	2.30 (0.95, N.A.)	1.972 (1.045, 3.723) 0.1249	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.9638
FEMALE	61	50 (82.0)	11 (18.0)	1.15 (0.89, 2.14)	55	37 (67.3)	18 (32.7)	2.27 (0.95, 3.22)	1.138 (0.739, 1.753) 0.3071	
MALE	215	143 (66.5)	72 (33.5)	2.40 (2.14, 3.52)	192	102 (53.1)	90 (46.9)	3.09 (2.23, 3.71)	1.115 (0.858, 1.450) 0.9743	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.5776
WHITE	193	143 (74.1)	50 (25.9)	2.10 (1.51, 2.33)	181	111 (61.3)	70 (38.7)	2.43 (2.10, 3.48)	1.191 (0.924, 1.534) 0.4584	
ASIAN	67	37 (55.2)	30 (44.8)	4.76 (2.40, 10.74)	53	22 (41.5)	31 (58.5)	N.A. (2.20, N.A.)	1.070 (0.621, 1.845) 0.8844	
OTHER	15	12 (80.0)	3 (20.0)	3.35 (0.76, 6.08)	11	6 (54.5)	5 (45.5)	2.04 (0.76, N.A.)	1.217 (0.369, 4.014) 0.6831	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.9679
US	16	9 (56.3)	7 (43.8)	2.50 (0.89, N.A.)	17	8 (47.1)	9 (52.9)	3.45 (1.45, N.A.)	1.427 (0.545, 3.738) 0.5423	
ASIA	66	37 (56.1)	29 (43.9)	4.76 (2.40, 10.74)	51	22 (43.1)	29 (56.9)	N.A. (2.20, N.A.)	1.073 (0.623, 1.849) 0.9465	
EUROPE	124	93 (75.0)	31 (25.0)	2.14 (1.61, 2.66)	115	74 (64.3)	41 (35.7)	2.37 (1.54, 3.48)	1.172 (0.852, 1.611) 0.7995	
REST OF THE WORLD	70	54 (77.1)	16 (22.9)	1.64 (1.02, 2.37)	64	35 (54.7)	29 (45.3)	2.60 (1.41, 4.01)	1.177 (0.760, 1.823) 0.2713	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.6658
0	152	107 (70.4)	45 (29.6)	2.33 (1.45, 2.50)	132	79 (59.8)	53 (40.2)	2.37 (2.07, 3.52)	1.195 (0.886, 1.612) 0.8826	
1	122	85 (69.7)	37 (30.3)	2.14 (1.77, 3.35)	115	60 (52.2)	55 (47.8)	3.09 (2.23, 3.75)	1.022 (0.728, 1.435) 0.5389	

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(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.3313
YES	58	41 (70.7)	17 (29.3)	1.41 (0.92, 2.66)	47	24 (51.1)	23 (48.9)	3.68 (1.41, N.A.)	1.378 (0.828, 2.296) 0.1906	
NO	218	152 (69.7)	66 (30.3)	2.37 (2.14, 2.83)	200	115 (57.5)	85 (42.5)	2.43 (2.17, 3.48)	1.068 (0.832, 1.372) 0.8700	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.7492
STAGE III	35	21 (60.0)	14 (40.0)	2.79 (0.85, N.A.)	17	11 (64.7)	6 (35.3)	3.09 (0.79, 3.58)	1.243 (0.538, 2.873) 0.3010	
STAGE IV	239	170 (71.1)	69 (28.9)	2.14 (1.77, 2.43)	229	127 (55.5)	102 (44.5)	2.76 (2.23, 3.55)	1.130 (0.893, 1.430) 0.3747	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.7149
YES	22	16 (72.7)	6 (27.3)	1.45 (0.89, 4.37)	18	12 (66.7)	6 (33.3)	1.61 (1.02, 4.01)	0.951 (0.439, 2.062) 0.9111	
NO	254	177 (69.7)	77 (30.3)	2.33 (2.10, 2.56)	229	127 (55.5)	102 (44.5)	2.79 (2.23, 3.58)	1.133 (0.897, 1.432) 0.5894	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.1779
YES	80	58 (72.5)	22 (27.5)	2.10 (1.02, 2.30)	53	28 (52.8)	25 (47.2)	2.79 (1.51, N.A.)	1.571 (0.993, 2.483) 0.1387	
NO	196	135 (68.9)	61 (31.1)	2.46 (2.14, 3.35)	194	111 (57.2)	83 (42.8)	2.76 (2.17, 3.55)	0.991 (0.764, 1.285) 0.6743	

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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.1080
>=1%	99	63 (63.6)	36 (36.4)	2.46 (2.14, 6.08)	82	47 (57.3)	35 (42.7)	2.86 (2.10, 3.75)	0.856 (0.578, 1.266) 0.4167	
<1%/ INDETERMINATE	177	130 (73.4)	47 (26.6)	2.14 (1.51, 2.40)	165	92 (55.8)	73 (44.2)	2.56 (2.14, 3.58)	1.285 (0.978, 1.688) 0.2330	

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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Fatigue (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.2203
YES	60	44 (73.3)	16 (26.7)	1.45 (0.95, 2.66)	49	25 (51.0)	24 (49.0)	3.68 (1.87, N.A.)	1.445 (0.879, 2.375) 0.1538	
NO	216	149 (69.0)	67 (31.0)	2.37 (2.14, 2.83)	198	114 (57.6)	84 (42.4)	2.40 (2.14, 3.48)	1.059 (0.824, 1.363) 0.8368	

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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	156 (56.5)	120 (43.5)	3.55 (2.40, 4.86)	247	114 (46.2)	133 (53.8)	3.78 (3.09, 4.60)	1.082 (0.846, 1.384) 0.4982	
PD-L1 STATUS										0.2829
>= 1%	100	53 (53.0)	47 (47.0)	4.44 (2.40, N.A.)	81	38 (46.9)	43 (53.1)	3.52 (2.20, N.A.)	0.921 (0.601, 1.411) 0.8347	
< 1%	176	103 (58.5)	73 (41.5)	3.09 (2.27, 4.86)	166	76 (45.8)	90 (54.2)	3.88 (2.83, N.A.)	1.180 (0.872, 1.597) 0.3267	

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Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.2707
< 65	139	78 (56.1)	61 (43.9)	3.19 (2.33, 6.44)	124	64 (51.6)	60 (48.4)	3.48 (2.27, 4.44)	0.914 (0.651, 1.282) 0.7827	
>= 65 AND < 75	108	59 (54.6)	49 (45.4)	4.37 (2.27, 23.16)	91	34 (37.4)	57 (62.6)	N.A. (3.45, N.A.)	1.363 (0.885, 2.097) 0.1922	
>= 75	29	19 (65.5)	10 (34.5)	2.56 (1.54, 4.83)	32	16 (50.0)	16 (50.0)	2.60 (2.17, N.A.)	1.169 (0.591, 2.314) 0.7470	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.0241*
FEMALE	61	45 (73.8)	16 (26.2)	2.33 (1.15, 3.09)	55	22 (40.0)	33 (60.0)	N.A. (2.23, N.A.)	1.758 (1.046, 2.952) 0.0215	
MALE	215	111 (51.6)	104 (48.4)	4.53 (2.46, N.A.)	192	92 (47.9)	100 (52.1)	3.55 (2.89, 4.44)	0.924 (0.697, 1.224) 0.5863	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.6983
WHITE	193	110 (57.0)	83 (43.0)	3.55 (2.40, 4.83)	181	85 (47.0)	96 (53.0)	3.81 (2.83, N.A.)	1.119 (0.840, 1.491) 0.4529	
ASIAN	67	35 (52.2)	32 (47.8)	3.09 (2.14, N.A.)	53	23 (43.4)	30 (56.6)	3.55 (2.23, N.A.)	1.102 (0.645, 1.883) 0.6802	
OTHER	15	11 (73.3)	4 (26.7)	4.53 (0.92, N.A.)	11	6 (54.5)	5 (45.5)	2.37 (0.72, N.A.)	0.610 (0.204, 1.825) 0.4121	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.9204
US	16	7 (43.8)	9 (56.3)	6.54 (0.76, N.A.)	17	10 (58.8)	7 (41.2)	3.35 (2.17, N.A.)	0.783 (0.288, 2.127) 0.5551	
ASIA	66	34 (51.5)	32 (48.5)	3.09 (2.14, N.A.)	51	21 (41.2)	30 (58.8)	4.60 (2.23, N.A.)	1.149 (0.661, 1.998) 0.6215	
EUROPE	124	68 (54.8)	56 (45.2)	4.44 (2.14, N.A.)	115	51 (44.3)	64 (55.7)	3.88 (2.37, N.A.)	1.078 (0.745, 1.560) 0.6364	
REST OF THE WORLD	70	47 (67.1)	23 (32.9)	2.79 (2.17, 4.24)	64	32 (50.0)	32 (50.0)	3.48 (2.20, N.A.)	1.171 (0.742, 1.850) 0.4808	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.9768
0	152	90 (59.2)	62 (40.8)	2.56 (2.27, 4.53)	132	68 (51.5)	64 (48.5)	3.55 (2.37, 4.44)	1.099 (0.798, 1.513) 0.6024	
1	122	65 (53.3)	57 (46.7)	4.47 (2.69, N.A.)	115	46 (40.0)	69 (60.0)	4.44 (2.83, N.A.)	1.067 (0.724, 1.571) 0.6837	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.1076
YES	58	35 (60.3)	23 (39.7)	2.10 (0.92, 3.55)	47	19 (40.4)	28 (59.6)	3.81 (2.23, N.A.)	1.693 (0.964, 2.974) 0.0501	
NO	218	121 (55.5)	97 (44.5)	4.37 (2.60, 6.67)	200	95 (47.5)	105 (52.5)	3.55 (3.09, 4.60)	0.961 (0.729, 1.266) 0.7591	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.6999
STAGE III	35	20 (57.1)	15 (42.9)	2.76 (2.10, N.A.)	17	9 (52.9)	8 (47.1)	3.45 (0.79, N.A.)	0.992 (0.449, 2.193) 0.9249	
STAGE IV	239	134 (56.1)	105 (43.9)	3.71 (2.40, 5.65)	229	104 (45.4)	125 (54.6)	3.81 (3.09, N.A.)	1.074 (0.827, 1.394) 0.5382	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.6332
YES	22	13 (59.1)	9 (40.9)	4.30 (1.68, N.A.)	18	8 (44.4)	10 (55.6)	4.01 (1.41, N.A.)	0.761 (0.297, 1.950) 0.5573	
NO	254	143 (56.3)	111 (43.7)	3.19 (2.40, 4.86)	229	106 (46.3)	123 (53.7)	3.78 (2.99, N.A.)	1.114 (0.863, 1.438) 0.3935	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.3231
YES	80	52 (65.0)	28 (35.0)	2.40 (2.04, 4.30)	53	26 (49.1)	27 (50.9)	3.55 (2.37, N.A.)	1.336 (0.826, 2.162) 0.2249	
NO	196	104 (53.1)	92 (46.9)	4.37 (2.56, 11.56)	194	88 (45.4)	106 (54.6)	3.81 (2.43, N.A.)	0.997 (0.746, 1.332) 0.9525	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.2868
>=1%	99	52 (52.5)	47 (47.5)	4.44 (2.40, N.A.)	82	38 (46.3)	44 (53.7)	3.52 (2.23, N.A.)	0.923 (0.601, 1.416) 0.8319	
<1%/ INDETERMINATE	177	104 (58.8)	73 (41.2)	3.09 (2.27, 4.83)	165	76 (46.1)	89 (53.9)	3.88 (2.60, 4.60)	1.182 (0.874, 1.598) 0.3204	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Nausea and Vomiting (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.1114
YES	60	36 (60.0)	24 (40.0)	2.14 (0.99, 4.17)	49	19 (38.8)	30 (61.2)	3.81 (2.23, N.A.)	1.668 (0.952, 2.924) 0.0577	
NO	216	120 (55.6)	96 (44.4)	4.30 (2.56, 6.67)	198	95 (48.0)	103 (52.0)	3.55 (2.99, 4.60)	0.963 (0.731, 1.269) 0.7784	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	142 (51.4)	134 (48.6)	6.74 (5.49, 8.97)	248	78 (31.5)	170 (68.5)	8.31 (4.40, N.A.)	1.044 (0.778, 1.401) 0.8632	
PD-L1 STATUS										0.7118
>= 1%	100	48 (48.0)	52 (52.0)	7.69 (5.65, 11.30)	82	24 (29.3)	58 (70.7)	N.A. (3.81, N.A.)	0.830 (0.489, 1.411) 0.4307	
< 1%	176	94 (53.4)	82 (46.6)	6.54 (4.60, 9.76)	166	54 (32.5)	112 (67.5)	8.31 (4.40, N.A.)	1.143 (0.803, 1.627) 0.4338	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.9801
< 65	139	71 (51.1)	68 (48.9)	6.97 (5.36, 8.97)	124	34 (27.4)	90 (72.6)	8.31 (4.60, N.A.)	1.110 (0.719, 1.715) 0.5276	
>= 65 AND < 75	108	55 (50.9)	53 (49.1)	8.74 (5.03, 10.74)	92	31 (33.7)	61 (66.3)	4.60 (3.81, N.A.)	0.995 (0.620, 1.597) 0.7823	
>= 75	29	16 (55.2)	13 (44.8)	4.83 (2.37, N.A.)	32	13 (40.6)	19 (59.4)	N.A. (1.61, N.A.)	1.044 (0.486, 2.243) 0.9205	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.9992
FEMALE	61	34 (55.7)	27 (44.3)	6.05 (4.14, 8.74)	55	17 (30.9)	38 (69.1)	4.60 (3.75, N.A.)	0.974 (0.518, 1.830) 0.8057	
MALE	215	108 (50.2)	107 (49.8)	7.13 (5.49, 10.74)	193	61 (31.6)	132 (68.4)	8.31 (4.40, N.A.)	1.058 (0.758, 1.478) 0.9682	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.2910
WHITE	193	99 (51.3)	94 (48.7)	6.37 (5.03, 8.61)	182	65 (35.7)	117 (64.3)	8.31 (4.04, 8.38)	0.952 (0.684, 1.324) 0.6890	
ASIAN	67	33 (49.3)	34 (50.7)	10.74 (6.08, 14.75)	53	11 (20.8)	42 (79.2)	N.A. (4.60, N.A.)	1.545 (0.746, 3.196) 0.2508	
OTHER	15	9 (60.0)	6 (40.0)	5.19 (1.41, N.A.)	11	2 (18.2)	9 (81.8)	N.A. (2.37, N.A.)	1.570 (0.279, 8.824) 0.8323	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.2930
US	16	4 (25.0)	12 (75.0)	N.A. (4.24, N.A.)	17	5 (29.4)	12 (70.6)	8.31 (3.61, N.A.)	0.595 (0.149, 2.378) 0.4486	
ASIA	66	33 (50.0)	33 (50.0)	9.53 (6.08, 14.75)	51	11 (21.6)	40 (78.4)	N.A. (4.60, N.A.)	1.573 (0.760, 3.253) 0.2670	
EUROPE	124	71 (57.3)	53 (42.7)	5.13 (3.55, 7.59)	116	38 (32.8)	78 (67.2)	N.A. (3.81, N.A.)	1.189 (0.788, 1.795) 0.3505	
REST OF THE WORLD	70	34 (48.6)	36 (51.4)	6.37 (5.26, N.A.)	64	24 (37.5)	40 (62.5)	4.07 (2.86, N.A.)	0.662 (0.372, 1.175) 0.1644	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.5617
0	152	76 (50.0)	76 (50.0)	7.69 (5.36, 14.75)	133	44 (33.1)	89 (66.9)	8.31 (4.04, N.A.)	0.986 (0.660, 1.472) 0.6019	
1	122	66 (54.1)	56 (45.9)	6.05 (4.34, 7.59)	115	34 (29.6)	81 (70.4)	8.38 (4.40, N.A.)	1.090 (0.707, 1.679) 0.3248	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.5922
YES	58	26 (44.8)	32 (55.2)	6.74 (2.53, N.A.)	48	19 (39.6)	29 (60.4)	4.04 (2.46, N.A.)	1.026 (0.560, 1.878) 0.8028	
NO	218	116 (53.2)	102 (46.8)	6.97 (5.65, 9.53)	200	59 (29.5)	141 (70.5)	8.38 (4.60, N.A.)	1.058 (0.756, 1.480) 0.7536	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.4003
STAGE III	35	17 (48.6)	18 (51.4)	6.44 (0.85, N.A.)	18	3 (16.7)	15 (83.3)	N.A.	2.384 (0.684, 8.305) 0.1346	
STAGE IV	239	123 (51.5)	116 (48.5)	7.00 (5.49, 9.53)	229	75 (32.8)	154 (67.2)	8.31 (4.40, N.A.)	0.960 (0.705, 1.306) 0.6439	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.7536
YES	22	14 (63.6)	8 (36.4)	2.63 (0.95, 6.74)	18	5 (27.8)	13 (72.2)	N.A. (1.48, N.A.)	1.041 (0.359, 3.024) 0.3803	
NO	254	128 (50.4)	126 (49.6)	7.13 (5.65, 9.76)	230	73 (31.7)	157 (68.3)	8.31 (4.40, N.A.)	1.008 (0.742, 1.371) 0.8682	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.0276*
YES	80	47 (58.8)	33 (41.3)	5.16 (2.99, 8.74)	53	11 (20.8)	42 (79.2)	8.38 (N.A., N.A.)	2.051 (1.042, 4.037) 0.0247	
NO	196	95 (48.5)	101 (51.5)	7.13 (6.08, 10.74)	195	67 (34.4)	128 (65.6)	4.60 (4.04, N.A.)	0.868 (0.619, 1.217) 0.2669	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.5906
>=1%	99	47 (47.5)	52 (52.5)	7.69 (5.65, 11.30)	83	25 (30.1)	58 (69.9)	N.A. (3.81, N.A.)	0.786 (0.464, 1.333) 0.3036	
<1%/ INDETERMINATE	177	95 (53.7)	82 (46.3)	6.54 (4.60, 9.76)	165	53 (32.1)	112 (67.9)	8.31 (4.40, N.A.)	1.167 (0.819, 1.663) 0.3559	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Pain (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.6946
YES	60	29 (48.3)	31 (51.7)	5.26 (2.53, N.A.)	50	20 (40.0)	30 (60.0)	4.04 (2.46, N.A.)	1.028 (0.574, 1.840) 0.8660	
NO	216	113 (52.3)	103 (47.7)	6.97 (6.05, 9.76)	198	58 (29.3)	140 (70.7)	8.38 (4.60, N.A.)	1.061 (0.756, 1.490) 0.7591	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	275	122 (44.4)	153 (55.6)	8.18 (6.24, 20.90)	246	87 (35.4)	159 (64.6)	5.62 (3.94, N.A.)	0.776 (0.580, 1.039) 0.0727	
PD-L1 STATUS										0.8410
>= 1%	100	43 (43.0)	57 (57.0)	8.11 (5.75, N.A.)	80	26 (32.5)	54 (67.5)	5.62 (3.75, N.A.)	0.665 (0.396, 1.117) 0.1128	
< 1%	175	79 (45.1)	96 (54.9)	8.28 (6.11, N.A.)	166	61 (36.7)	105 (63.3)	9.46 (3.84, N.A.)	0.857 (0.603, 1.220) 0.3451	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.4340
< 65	138	61 (44.2)	77 (55.8)	6.97 (5.42, N.A.)	124	45 (36.3)	79 (63.7)	4.60 (3.75, N.A.)	0.680 (0.450, 1.028) 0.0794	
>= 65 AND < 75	108	47 (43.5)	61 (56.5)	13.27 (5.95, 20.90)	91	34 (37.4)	57 (62.6)	N.A. (3.71, N.A.)	0.733 (0.457, 1.175) 0.1349	
>= 75	29	14 (48.3)	15 (51.7)	8.28 (2.40, N.A.)	31	8 (25.8)	23 (74.2)	N.A. (3.78, N.A.)	1.565 (0.644, 3.804) 0.3295	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.8317
FEMALE	61	27 (44.3)	34 (55.7)	13.27 (5.29, N.A.)	54	19 (35.2)	35 (64.8)	N.A. (3.52, N.A.)	0.736 (0.391, 1.383) 0.3480	
MALE	214	95 (44.4)	119 (55.6)	8.11 (5.95, N.A.)	192	68 (35.4)	124 (64.6)	4.60 (3.81, N.A.)	0.785 (0.565, 1.091) 0.1244	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.3812
WHITE	192	80 (41.7)	112 (58.3)	14.98 (6.54, N.A.)	181	69 (38.1)	112 (61.9)	4.60 (3.81, N.A.)	0.692 (0.491, 0.974) 0.0281	
ASIAN	67	32 (47.8)	35 (52.2)	7.03 (4.76, N.A.)	53	15 (28.3)	38 (71.7)	N.A. (3.75, N.A.)	1.066 (0.560, 2.028) 0.8650	
OTHER	15	10 (66.7)	5 (33.3)	5.75 (1.41, N.A.)	10	3 (30.0)	7 (70.0)	N.A. (0.76, N.A.)	0.856 (0.202, 3.626) 0.7665	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.7480
US	15	5 (33.3)	10 (66.7)	7.39 (2.37, N.A.)	17	5 (29.4)	12 (70.6)	N.A. (0.99, N.A.)	0.759 (0.211, 2.732) 0.4947	
ASIA	66	32 (48.5)	34 (51.5)	6.44 (4.60, N.A.)	51	15 (29.4)	36 (70.6)	N.A. (3.75, N.A.)	1.044 (0.550, 1.983) 0.9048	
EUROPE	124	52 (41.9)	72 (58.1)	14.98 (5.91, N.A.)	114	42 (36.8)	72 (63.2)	4.07 (3.75, N.A.)	0.714 (0.464, 1.098) 0.1037	
REST OF THE WORLD	70	33 (47.1)	37 (52.9)	7.13 (4.80, N.A.)	64	25 (39.1)	39 (60.9)	5.62 (3.48, N.A.)	0.688 (0.390, 1.213) 0.2048	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.3301
0	151	73 (48.3)	78 (51.7)	7.13 (5.42, N.A.)	132	48 (36.4)	84 (63.6)	5.62 (3.78, N.A.)	0.909 (0.617, 1.338) 0.4546	
1	122	47 (38.5)	75 (61.5)	14.98 (6.44, N.A.)	114	39 (34.2)	75 (65.8)	4.60 (3.94, N.A.)	0.644 (0.411, 1.010) 0.0665	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.7159
YES	58	27 (46.6)	31 (53.4)	8.18 (2.53, N.A.)	47	18 (38.3)	29 (61.7)	9.46 (2.17, N.A.)	0.719 (0.381, 1.356) 0.6566	
NO	217	95 (43.8)	122 (56.2)	13.27 (6.44, N.A.)	199	69 (34.7)	130 (65.3)	5.62 (3.94, N.A.)	0.769 (0.552, 1.072) 0.0652	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.5469
STAGE III	35	12 (34.3)	23 (65.7)	N.A. (5.16, N.A.)	17	6 (35.3)	11 (64.7)	N.A. (1.22, N.A.)	0.668 (0.238, 1.873) 0.3216	
STAGE IV	238	108 (45.4)	130 (54.6)	8.18 (6.11, 20.90)	228	81 (35.5)	147 (64.5)	5.62 (3.94, N.A.)	0.783 (0.576, 1.063) 0.1082	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.0788
YES	22	16 (72.7)	6 (27.3)	2.23 (1.02, 6.21)	18	6 (33.3)	12 (66.7)	4.21 (2.10, N.A.)	1.454 (0.544, 3.881) 0.4313	
NO	253	106 (41.9)	147 (58.1)	13.27 (6.97, N.A.)	228	81 (35.5)	147 (64.5)	5.62 (3.84, N.A.)	0.715 (0.526, 0.973) 0.0274	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.7125
YES	80	36 (45.0)	44 (55.0)	9.13 (5.62, N.A.)	52	21 (40.4)	31 (59.6)	N.A. (3.25, N.A.)	0.731 (0.415, 1.285) 0.2667	
NO	195	86 (44.1)	109 (55.9)	8.28 (6.44, N.A.)	194	66 (34.0)	128 (66.0)	5.62 (3.94, N.A.)	0.784 (0.556, 1.104) 0.1362	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.6424
>=1%	99	42 (42.4)	57 (57.6)	8.11 (5.75, N.A.)	81	27 (33.3)	54 (66.7)	5.62 (3.75, N.A.)	0.627 (0.374, 1.051) 0.0682	
<1%/ INDETERMINATE	176	80 (45.5)	96 (54.5)	8.28 (6.11, N.A.)	165	60 (36.4)	105 (63.6)	9.46 (3.84, N.A.)	0.881 (0.619, 1.254) 0.4317	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Dyspnea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.9390
YES	60	28 (46.7)	32 (53.3)	8.18 (2.53, N.A.)	49	17 (34.7)	32 (65.3)	9.46 (2.37, N.A.)	0.819 (0.433, 1.549) 0.9678	
NO	215	94 (43.7)	121 (56.3)	9.13 (6.44, N.A.)	197	70 (35.5)	127 (64.5)	4.60 (3.94, N.A.)	0.744 (0.534, 1.037) 0.0410	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	275	112 (40.7)	163 (59.3)	11.27 (9.46, N.A.)	247	77 (31.2)	170 (68.8)	8.38 (8.38, N.A.)	0.825 (0.606, 1.123) 0.1828	
PD-L1 STATUS										0.4881
>= 1%	100	36 (36.0)	64 (64.0)	18.99 (7.69, N.A.)	81	24 (29.6)	57 (70.4)	N.A. (5.16, N.A.)	0.735 (0.425, 1.272) 0.2460	
< 1%	175	76 (43.4)	99 (56.6)	9.82 (8.31, N.A.)	166	53 (31.9)	113 (68.1)	8.38 (8.38, N.A.)	0.872 (0.600, 1.265) 0.4325	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.3740
< 65	138	55 (39.9)	83 (60.1)	11.27 (7.69, N.A.)	124	37 (29.8)	87 (70.2)	N.A. (3.94, N.A.)	0.936 (0.605, 1.447) 0.7687	
>= 65 AND < 75	108	45 (41.7)	63 (58.3)	10.74 (9.46, N.A.)	91	24 (26.4)	67 (73.6)	8.38 (N.A., N.A.)	0.881 (0.515, 1.508) 0.6967	
>= 75	29	12 (41.4)	17 (58.6)	18.99 (6.54, N.A.)	32	16 (50.0)	16 (50.0)	2.63 (1.45, N.A.)	0.448 (0.193, 1.041) 0.0261	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.0142*
FEMALE	61	34 (55.7)	27 (44.3)	6.24 (2.66, 18.99)	55	14 (25.5)	41 (74.5)	N.A.	1.499 (0.782, 2.872) 0.1208	
MALE	214	78 (36.4)	136 (63.6)	12.62 (9.72, N.A.)	192	63 (32.8)	129 (67.2)	8.38 (5.16, N.A.)	0.667 (0.467, 0.953) 0.0150	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.7752
WHITE	192	82 (42.7)	110 (57.3)	11.27 (8.31, 19.09)	181	60 (33.1)	121 (66.9)	8.38 (8.38, N.A.)	0.859 (0.604, 1.221) 0.3738	
ASIAN	67	23 (34.3)	44 (65.7)	10.74 (9.53, N.A.)	53	14 (26.4)	39 (73.6)	N.A. (5.16, N.A.)	0.743 (0.364, 1.516) 0.5021	
OTHER	15	7 (46.7)	8 (53.3)	9.82 (4.37, N.A.)	11	3 (27.3)	8 (72.7)	N.A. (0.76, N.A.)	0.367 (0.051, 2.630) 0.1738	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.9640
US	16	5 (31.3)	11 (68.8)	N.A. (1.12, N.A.)	17	6 (35.3)	11 (64.7)	8.38 (2.23, N.A.)	0.729 (0.217, 2.454) 0.7455	
ASIA	66	23 (34.8)	43 (65.2)	10.74 (7.69, N.A.)	51	14 (27.5)	37 (72.5)	N.A. (5.16, N.A.)	0.751 (0.368, 1.531) 0.4628	
EUROPE	123	55 (44.7)	68 (55.3)	9.82 (7.46, N.A.)	115	36 (31.3)	79 (68.7)	N.A. (3.94, N.A.)	0.859 (0.548, 1.348) 0.3994	
REST OF THE WORLD	70	29 (41.4)	41 (58.6)	14.36 (5.13, N.A.)	64	21 (32.8)	43 (67.2)	N.A. (3.94, N.A.)	0.993 (0.547, 1.801) 0.6224	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.5147
0	151	61 (40.4)	90 (59.6)	14.36 (9.10, N.A.)	132	46 (34.8)	86 (65.2)	N.A. (3.94, N.A.)	0.783 (0.519, 1.182) 0.1650	
1	122	50 (41.0)	72 (59.0)	9.82 (6.90, N.A.)	115	31 (27.0)	84 (73.0)	8.38 (5.16, N.A.)	0.900 (0.563, 1.437) 0.7372	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.9978
YES	57	21 (36.8)	36 (63.2)	N.A. (5.52, N.A.)	47	17 (36.2)	30 (63.8)	5.16 (3.55, N.A.)	0.893 (0.466, 1.709) 0.5260	
NO	218	91 (41.7)	127 (58.3)	11.27 (9.53, N.A.)	200	60 (30.0)	140 (70.0)	8.38 (8.38, N.A.)	0.803 (0.565, 1.142) 0.2229	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.9045
STAGE III	34	13 (38.2)	21 (61.8)	N.A. (6.24, N.A.)	17	4 (23.5)	13 (76.5)	N.A. (2.53, N.A.)	0.950 (0.291, 3.099) 0.8078	
STAGE IV	239	98 (41.0)	141 (59.0)	11.27 (9.53, N.A.)	229	73 (31.9)	156 (68.1)	8.38 (8.38, N.A.)	0.832 (0.602, 1.148) 0.1698	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.7673
YES	22	11 (50.0)	11 (50.0)	5.65 (1.68, N.A.)	18	7 (38.9)	11 (61.1)	N.A. (1.41, N.A.)	0.632 (0.215, 1.861) 0.3617	
NO	253	101 (39.9)	152 (60.1)	12.62 (9.53, N.A.)	229	70 (30.6)	159 (69.4)	8.38 (8.38, N.A.)	0.828 (0.599, 1.145) 0.2249	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.6287
YES	79	34 (43.0)	45 (57.0)	14.36 (4.57, N.A.)	53	15 (28.3)	38 (71.7)	8.38 (5.16, N.A.)	1.033 (0.551, 1.935) 0.6832	
NO	196	78 (39.8)	118 (60.2)	10.94 (9.46, N.A.)	194	62 (32.0)	132 (68.0)	N.A.	0.785 (0.548, 1.124) 0.0848	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.4473
>=1%	99	36 (36.4)	63 (63.6)	18.99 (7.69, N.A.)	82	25 (30.5)	57 (69.5)	N.A. (5.16, N.A.)	0.721 (0.419, 1.240) 0.2165	
<1%/ INDETERMINATE	176	76 (43.2)	100 (56.8)	9.82 (8.31, N.A.)	165	52 (31.5)	113 (68.5)	8.38 (8.38, N.A.)	0.878 (0.604, 1.277) 0.4516	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Insomnia (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.7951
YES	59	23 (39.0)	36 (61.0)	18.99 (5.52, N.A.)	49	17 (34.7)	32 (65.3)	5.16 (3.55, N.A.)	0.936 (0.492, 1.780) 0.6234	
NO	216	89 (41.2)	127 (58.8)	11.27 (9.46, N.A.)	198	60 (30.3)	138 (69.7)	8.38 (8.38, N.A.)	0.789 (0.554, 1.123) 0.1895	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	144 (52.2)	132 (47.8)	6.21 (3.84, 9.53)	248	90 (36.3)	158 (63.7)	8.11 (3.94, N.A.)	1.111 (0.847, 1.457) 0.4991	
PD-L1 STATUS										0.7611
>= 1%	100	46 (46.0)	54 (54.0)	6.54 (3.52, N.A.)	82	23 (28.0)	59 (72.0)	N.A. (4.60, N.A.)	1.109 (0.666, 1.847) 0.5055	
< 1%	176	98 (55.7)	78 (44.3)	4.76 (2.79, 9.13)	166	67 (40.4)	99 (59.6)	8.11 (3.65, N.A.)	1.131 (0.819, 1.562) 0.6383	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.4897
< 65	139	69 (49.6)	70 (50.4)	6.21 (3.06, N.A.)	124	43 (34.7)	81 (65.3)	8.11 (3.84, N.A.)	1.013 (0.686, 1.496) 0.5168	
>= 65 AND < 75	108	59 (54.6)	49 (45.4)	6.24 (3.75, 14.06)	92	31 (33.7)	61 (66.3)	N.A. (3.25, N.A.)	1.296 (0.822, 2.043) 0.6363	
>= 75	29	16 (55.2)	13 (44.8)	2.99 (1.41, N.A.)	32	16 (50.0)	16 (50.0)	3.68 (1.61, N.A.)	1.285 (0.620, 2.662) 0.9846	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.9992
FEMALE	61	36 (59.0)	25 (41.0)	3.09 (2.33, 9.53)	55	24 (43.6)	31 (56.4)	4.21 (2.37, N.A.)	1.154 (0.682, 1.953) 0.5361	
MALE	215	108 (50.2)	107 (49.8)	6.54 (4.34, 14.06)	193	66 (34.2)	127 (65.8)	8.11 (3.94, N.A.)	1.093 (0.796, 1.500) 0.6866	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.8028
WHITE	193	97 (50.3)	96 (49.7)	6.28 (4.01, 23.29)	182	69 (37.9)	113 (62.1)	8.11 (3.84, N.A.)	1.068 (0.777, 1.469) 0.8774	
ASIAN	67	37 (55.2)	30 (44.8)	4.70 (2.43, 9.53)	53	18 (34.0)	35 (66.0)	N.A. (3.02, N.A.)	1.131 (0.635, 2.014) 0.5156	
OTHER	15	9 (60.0)	6 (40.0)	2.60 (0.92, N.A.)	11	3 (27.3)	8 (72.7)	N.A. (0.76, N.A.)	1.701 (0.450, 6.429) 0.5358	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.9679
US	16	6 (37.5)	10 (62.5)	N.A. (0.99, N.A.)	17	5 (29.4)	12 (70.6)	N.A. (1.51, N.A.)	1.304 (0.383, 4.441) 0.9030	
ASIA	66	37 (56.1)	29 (43.9)	4.70 (2.43, 9.53)	51	18 (35.3)	33 (64.7)	3.94 (3.02, N.A.)	1.146 (0.644, 2.039) 0.5527	
EUROPE	124	65 (52.4)	59 (47.6)	4.73 (2.60, 23.29)	116	43 (37.1)	73 (62.9)	N.A. (3.68, N.A.)	1.158 (0.778, 1.723) 0.5965	
REST OF THE WORLD	70	36 (51.4)	34 (48.6)	6.21 (3.06, N.A.)	64	24 (37.5)	40 (62.5)	8.11 (3.48, N.A.)	0.958 (0.561, 1.635) 0.9493	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.8254
0	152	78 (51.3)	74 (48.7)	6.54 (3.09, N.A.)	133	49 (36.8)	84 (63.2)	N.A. (3.84, N.A.)	1.171 (0.812, 1.688) 0.5658	
1	122	66 (54.1)	56 (45.9)	4.99 (2.83, 9.53)	115	41 (35.7)	74 (64.3)	8.11 (3.25, N.A.)	0.997 (0.664, 1.497) 0.6278	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.4604
YES	58	25 (43.1)	33 (56.9)	7.26 (3.75, N.A.)	48	17 (35.4)	31 (64.6)	N.A. (2.23, N.A.)	0.878 (0.465, 1.660) 0.9051	
NO	218	119 (54.6)	99 (45.4)	6.08 (3.06, 9.53)	200	73 (36.5)	127 (63.5)	8.11 (3.94, N.A.)	1.165 (0.863, 1.574) 0.3873	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.2671
STAGE III	35	15 (42.9)	20 (57.1)	N.A. (2.53, N.A.)	18	8 (44.4)	10 (55.6)	4.60 (1.51, N.A.)	0.778 (0.325, 1.862) 0.5492	
STAGE IV	239	127 (53.1)	112 (46.9)	6.21 (3.75, 9.53)	229	82 (35.8)	147 (64.2)	8.11 (3.94, N.A.)	1.121 (0.842, 1.494) 0.4825	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.2082
YES	22	9 (40.9)	13 (59.1)	N.A. (1.61, N.A.)	18	9 (50.0)	9 (50.0)	2.40 (1.35, N.A.)	0.670 (0.256, 1.750) 0.2946	
NO	254	135 (53.1)	119 (46.9)	4.99 (3.52, 9.13)	230	81 (35.2)	149 (64.8)	8.11 (3.94, N.A.)	1.163 (0.876, 1.544) 0.3082	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.6388
YES	80	45 (56.3)	35 (43.8)	4.27 (2.43, 6.37)	53	20 (37.7)	33 (62.3)	N.A. (3.09, N.A.)	1.204 (0.706, 2.056) 0.4491	
NO	196	99 (50.5)	97 (49.5)	6.97 (3.32, 23.29)	195	70 (35.9)	125 (64.1)	8.11 (3.94, N.A.)	1.084 (0.789, 1.488) 0.7537	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.7932
>=1%	99	45 (45.5)	54 (54.5)	6.97 (3.75, N.A.)	83	23 (27.7)	60 (72.3)	N.A. (4.60, N.A.)	1.117 (0.670, 1.864) 0.5168	
<1%/ INDETERMINATE	177	99 (55.9)	78 (44.1)	4.70 (2.60, 9.13)	165	67 (40.6)	98 (59.4)	8.11 (3.65, N.A.)	1.129 (0.818, 1.558) 0.6308	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Appetite Loss (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.3232
YES	60	26 (43.3)	34 (56.7)	7.26 (4.24, N.A.)	50	18 (36.0)	32 (64.0)	N.A. (2.46, N.A.)	0.800 (0.426, 1.500) 0.7128	
NO	216	118 (54.6)	98 (45.4)	4.76 (3.06, 9.13)	198	72 (36.4)	126 (63.6)	8.11 (3.94, N.A.)	1.189 (0.879, 1.608) 0.3235	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	108 (39.1)	168 (60.9)	18.56 (9.86, N.A.)	245	88 (35.9)	157 (64.1)	8.11 (4.44, N.A.)	0.739 (0.550, 0.992) 0.0465	
PD-L1 STATUS										0.5304
>= 1%	100	42 (42.0)	58 (58.0)	18.33 (5.65, N.A.)	80	27 (33.8)	53 (66.3)	N.A. (3.58, N.A.)	0.803 (0.486, 1.328) 0.3829	
< 1%	176	66 (37.5)	110 (62.5)	20.53 (9.86, N.A.)	165	61 (37.0)	104 (63.0)	8.11 (3.81, N.A.)	0.714 (0.495, 1.028) 0.0731	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.1875
< 65	139	48 (34.5)	91 (65.5)	N.A. (8.54, N.A.)	123	49 (39.8)	74 (60.2)	4.70 (3.58, N.A.)	0.539 (0.353, 0.822) 0.0013	
>= 65 AND < 75	108	45 (41.7)	63 (58.3)	17.12 (8.18, N.A.)	90	29 (32.2)	61 (67.8)	N.A.	0.958 (0.589, 1.557) 0.9062	
>= 75	29	15 (51.7)	14 (48.3)	3.84 (1.61, N.A.)	32	10 (31.3)	22 (68.8)	N.A. (2.30, N.A.)	1.273 (0.568, 2.853) 0.2302	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.8548
FEMALE	61	27 (44.3)	34 (55.7)	19.09 (4.37, N.A.)	55	22 (40.0)	33 (60.0)	N.A. (2.40, N.A.)	0.754 (0.422, 1.346) 0.3239	
MALE	215	81 (37.7)	134 (62.3)	18.56 (9.86, N.A.)	190	66 (34.7)	124 (65.3)	8.11 (4.44, N.A.)	0.736 (0.523, 1.036) 0.0837	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.3908
WHITE	193	79 (40.9)	114 (59.1)	18.56 (8.21, N.A.)	179	66 (36.9)	113 (63.1)	8.11 (4.44, N.A.)	0.773 (0.550, 1.087) 0.1507	
ASIAN	67	24 (35.8)	43 (64.2)	N.A. (8.54, N.A.)	53	16 (30.2)	37 (69.8)	N.A. (3.55, N.A.)	0.786 (0.399, 1.548) 0.4532	
OTHER	15	5 (33.3)	10 (66.7)	N.A. (2.37, N.A.)	11	5 (45.5)	6 (54.5)	2.37 (0.76, N.A.)	0.387 (0.110, 1.370) 0.1871	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.9121
US	16	7 (43.8)	9 (56.3)	N.A. (0.99, N.A.)	17	7 (41.2)	10 (58.8)	N.A. (0.82, N.A.)	0.905 (0.296, 2.763) 0.7090	
ASIA	66	23 (34.8)	43 (65.2)	N.A. (8.54, N.A.)	51	16 (31.4)	35 (68.6)	N.A. (3.55, N.A.)	0.752 (0.378, 1.495) 0.3370	
EUROPE	124	46 (37.1)	78 (62.9)	20.53 (9.86, N.A.)	115	38 (33.0)	77 (67.0)	N.A. (3.81, N.A.)	0.765 (0.489, 1.196) 0.3095	
REST OF THE WORLD	70	32 (45.7)	38 (54.3)	17.12 (3.84, N.A.)	62	27 (43.5)	35 (56.5)	4.44 (2.20, N.A.)	0.688 (0.404, 1.174) 0.1687	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.5615
0	152	64 (42.1)	88 (57.9)	18.56 (8.21, N.A.)	130	53 (40.8)	77 (59.2)	4.44 (3.58, N.A.)	0.680 (0.462, 1.001) 0.0534	
1	122	44 (36.1)	78 (63.9)	19.09 (7.13, N.A.)	115	35 (30.4)	80 (69.6)	8.11 (4.70, N.A.)	0.837 (0.529, 1.323) 0.4826	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.6952
YES	58	20 (34.5)	38 (65.5)	18.33 (5.16, N.A.)	45	14 (31.1)	31 (68.9)	N.A. (2.37, N.A.)	0.797 (0.395, 1.606) 0.4946	
NO	218	88 (40.4)	130 (59.6)	19.09 (9.86, N.A.)	200	74 (37.0)	126 (63.0)	8.11 (4.44, N.A.)	0.724 (0.523, 1.003) 0.0592	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.8594
STAGE III	35	14 (40.0)	21 (60.0)	N.A. (2.17, N.A.)	17	7 (41.2)	10 (58.8)	N.A. (2.14, N.A.)	0.843 (0.332, 2.142) 0.8924	
STAGE IV	239	92 (38.5)	147 (61.5)	18.56 (11.30, N.A.)	227	80 (35.2)	147 (64.8)	8.11 (4.44, N.A.)	0.711 (0.518, 0.975) 0.0293	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.7051
YES	22	9 (40.9)	13 (59.1)	N.A. (2.40, N.A.)	18	7 (38.9)	11 (61.1)	N.A. (0.85, N.A.)	0.698 (0.257, 1.900) 0.5273	
NO	254	99 (39.0)	155 (61.0)	18.56 (9.86, N.A.)	227	81 (35.7)	146 (64.3)	8.11 (4.44, N.A.)	0.735 (0.540, 1.000) 0.0525	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.9457
YES	80	38 (47.5)	42 (52.5)	11.30 (2.69, N.A.)	53	25 (47.2)	28 (52.8)	3.55 (3.09, N.A.)	0.736 (0.434, 1.246) 0.3562	
NO	196	70 (35.7)	126 (64.3)	20.53 (18.33, N.A.)	192	63 (32.8)	129 (67.2)	8.11 (8.11, N.A.)	0.713 (0.498, 1.020) 0.0526	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.5771
>=1%	99	42 (42.4)	57 (57.6)	18.33 (5.65, N.A.)	81	28 (34.6)	53 (65.4)	N.A. (3.58, N.A.)	0.787 (0.479, 1.294) 0.3430	
<1%/ INDETERMINATE	177	66 (37.3)	111 (62.7)	20.53 (9.86, N.A.)	164	60 (36.6)	104 (63.4)	8.11 (3.81, N.A.)	0.719 (0.498, 1.038) 0.0797	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Constipation (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.4100
YES	60	22 (36.7)	38 (63.3)	18.33 (5.16, N.A.)	47	13 (27.7)	34 (72.3)	N.A. (3.81, N.A.)	0.891 (0.440, 1.806) 0.7803	
NO	216	86 (39.8)	130 (60.2)	19.09 (11.30, N.A.)	198	75 (37.9)	123 (62.1)	8.11 (3.78, N.A.)	0.709 (0.512, 0.983) 0.0402	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	275	72 (26.2)	203 (73.8)	N.A. (19.09, N.A.)	245	61 (24.9)	184 (75.1)	N.A. (8.11, N.A.)	0.473 (0.322, 0.696) <0.0001	
PD-L1 STATUS										0.9607
>= 1%	100	22 (22.0)	78 (78.0)	N.A. (16.07, N.A.)	80	16 (20.0)	64 (80.0)	N.A. (4.70, N.A.)	0.434 (0.205, 0.919) 0.0156	
< 1%	175	50 (28.6)	125 (71.4)	23.16 (19.06, N.A.)	165	45 (27.3)	120 (72.7)	N.A. (8.11, N.A.)	0.503 (0.322, 0.788) 0.0021	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.3424
< 65	138	33 (23.9)	105 (76.1)	N.A. (16.07, N.A.)	123	33 (26.8)	90 (73.2)	8.11 (8.11, N.A.)	0.404 (0.233, 0.699) 0.0003	
>= 65 AND < 75	108	32 (29.6)	76 (70.4)	23.16 (19.09, N.A.)	90	18 (20.0)	72 (80.0)	N.A.	0.689 (0.365, 1.301) 0.3114	
>= 75	29	7 (24.1)	22 (75.9)	N.A. (8.34, N.A.)	32	10 (31.3)	22 (68.8)	4.24 (2.83, N.A.)	0.278 (0.088, 0.873) 0.0271	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.2927
FEMALE	60	16 (26.7)	44 (73.3)	23.16 (12.68, N.A.)	55	17 (30.9)	38 (69.1)	N.A. (3.84, N.A.)	0.311 (0.135, 0.715) 0.0041	
MALE	215	56 (26.0)	159 (74.0)	N.A. (19.06, N.A.)	190	44 (23.2)	146 (76.8)	N.A. (8.11, N.A.)	0.537 (0.345, 0.833) 0.0028	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.8047
WHITE	192	53 (27.6)	139 (72.4)	N.A. (19.09, N.A.)	179	49 (27.4)	130 (72.6)	8.11 (8.11, N.A.)	0.508 (0.331, 0.781) 0.0013	
ASIAN	67	16 (23.9)	51 (76.1)	N.A. (8.87, N.A.)	53	10 (18.9)	43 (81.1)	N.A. (4.24, N.A.)	0.413 (0.160, 1.069) 0.0552	
OTHER	15	3 (20.0)	12 (80.0)	16.07 (11.56, N.A.)	11	2 (18.2)	9 (81.8)	N.A. (2.37, N.A.)	0.262 (0.023, 2.950) 0.2404	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.0872
US	16	5 (31.3)	11 (68.8)	N.A. (2.14, N.A.)	17	2 (11.8)	15 (88.2)	N.A.	4.126 (0.772, 22.045) 0.3367	
ASIA	66	16 (24.2)	50 (75.8)	N.A. (8.87, N.A.)	51	9 (17.6)	42 (82.4)	N.A. (4.24, N.A.)	0.454 (0.171, 1.205) 0.0905	
EUROPE	124	34 (27.4)	90 (72.6)	N.A. (19.06, N.A.)	115	31 (27.0)	84 (73.0)	N.A. (4.70, N.A.)	0.404 (0.232, 0.705) 0.0008	
REST OF THE WORLD	69	17 (24.6)	52 (75.4)	23.16 (16.07, N.A.)	62	19 (30.6)	43 (69.4)	8.11 (4.04, N.A.)	0.463 (0.225, 0.956) 0.0325	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.5209
0	152	41 (27.0)	111 (73.0)	N.A. (19.06, N.A.)	131	35 (26.7)	96 (73.3)	N.A.	0.438 (0.259, 0.741) 0.0012	
1	121	31 (25.6)	90 (74.4)	23.16 (19.09, N.A.)	114	26 (22.8)	88 (77.2)	8.11 (4.70, N.A.)	0.546 (0.310, 0.961) 0.0307	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.7791
YES	58	10 (17.2)	48 (82.8)	N.A.	46	12 (26.1)	34 (73.9)	N.A. (3.84, N.A.)	0.521 (0.221, 1.228) 0.1106	
NO	217	62 (28.6)	155 (71.4)	23.16 (19.06, N.A.)	199	49 (24.6)	150 (75.4)	8.11 (8.11, N.A.)	0.439 (0.283, 0.679) 0.0001	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.8259
STAGE III	35	9 (25.7)	26 (74.3)	N.A. (7.13, N.A.)	18	4 (22.2)	14 (77.8)	N.A. (2.60, N.A.)	0.393 (0.101, 1.527) 0.1691	
STAGE IV	238	63 (26.5)	175 (73.5)	23.16 (19.06, N.A.)	226	57 (25.2)	169 (74.8)	N.A. (8.11, N.A.)	0.489 (0.327, 0.731) 0.0002	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.4514
YES	22	6 (27.3)	16 (72.7)	N.A. (6.51, N.A.)	18	7 (38.9)	11 (61.1)	4.07 (2.10, N.A.)	0.268 (0.076, 0.941) 0.0283	
NO	253	66 (26.1)	187 (73.9)	N.A. (19.09, N.A.)	227	54 (23.8)	173 (76.2)	N.A. (8.11, N.A.)	0.497 (0.331, 0.746) 0.0004	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.7526
YES	80	25 (31.3)	55 (68.8)	19.09 (9.03, N.A.)	53	15 (28.3)	38 (71.7)	N.A. (4.70, N.A.)	0.428 (0.208, 0.881) 0.0202	
NO	195	47 (24.1)	148 (75.9)	N.A. (20.53, N.A.)	192	46 (24.0)	146 (76.0)	8.11 (8.11, N.A.)	0.475 (0.300, 0.752) 0.0008	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.9339
>=1%	99	21 (21.2)	78 (78.8)	N.A. (19.09, N.A.)	81	16 (19.8)	65 (80.2)	N.A. (4.70, N.A.)	0.446 (0.211, 0.945) 0.0189	
<1%/ INDETERMINATE	176	51 (29.0)	125 (71.0)	23.16 (16.07, N.A.)	164	45 (27.4)	119 (72.6)	N.A. (8.11, N.A.)	0.496 (0.317, 0.776) 0.0017	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Diarrhea (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.9390
YES	60	12 (20.0)	48 (80.0)	N.A. (7.13, N.A.)	48	13 (27.1)	35 (72.9)	N.A. (3.84, N.A.)	0.534 (0.238, 1.199) 0.1149	
NO	215	60 (27.9)	155 (72.1)	23.16 (19.06, N.A.)	197	48 (24.4)	149 (75.6)	8.11 (8.11, N.A.)	0.441 (0.283, 0.687) 0.0001	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Anhang 4-G-1.4.1.4: Subgruppenanalysen für die Endpunkte zur Lebensqualität – Globaler Gesundheitsstatus und Funktionsskalen gemäß EORTC QLQ-C30

Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	144 (52.2)	132 (47.8)	6.24 (4.57, 9.36)	246	113 (45.9)	133 (54.1)	3.78 (3.58, 4.60)	0.741 (0.571, 0.962) 0.0157	
PD-L1 STATUS										0.4179
>= 1%	100	44 (44.0)	56 (56.0)	9.36 (5.22, N.A.)	80	32 (40.0)	48 (60.0)	4.50 (2.46, N.A.)	0.697 (0.434, 1.120) 0.1573	
< 1%	176	100 (56.8)	76 (43.2)	4.99 (4.24, 7.46)	166	81 (48.8)	85 (51.2)	3.78 (3.52, 4.44)	0.772 (0.565, 1.056) 0.0602	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.6684
< 65	139	66 (47.5)	73 (52.5)	6.44 (4.96, N.A.)	124	51 (41.1)	73 (58.9)	4.60 (3.58, 8.11)	0.699 (0.475, 1.029) 0.0711	
>= 65 AND < 75	108	58 (53.7)	50 (46.3)	6.24 (4.37, 9.76)	90	38 (42.2)	52 (57.8)	3.75 (3.48, N.A.)	0.880 (0.571, 1.356) 0.4021	
>= 75	29	20 (69.0)	9 (31.0)	2.07 (0.95, 6.54)	32	24 (75.0)	8 (25.0)	2.46 (1.38, 3.78)	0.825 (0.443, 1.534) 0.4794	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.5106
FEMALE	61	38 (62.3)	23 (37.7)	4.21 (2.07, 7.03)	54	30 (55.6)	24 (44.4)	3.58 (2.17, 4.44)	0.915 (0.557, 1.501) 0.6409	
MALE	215	106 (49.3)	109 (50.7)	6.37 (4.96, 11.27)	192	83 (43.2)	109 (56.8)	4.01 (3.58, 8.11)	0.694 (0.511, 0.943) 0.0137	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.6032
WHITE	193	102 (52.8)	91 (47.2)	5.22 (4.34, 10.38)	180	91 (50.6)	89 (49.4)	3.71 (2.86, 4.37)	0.724 (0.539, 0.974) 0.0187	
ASIAN	67	32 (47.8)	35 (52.2)	8.34 (4.60, 11.30)	53	17 (32.1)	36 (67.9)	4.44 (3.68, N.A.)	0.832 (0.439, 1.579) 0.5214	
OTHER	15	9 (60.0)	6 (40.0)	4.37 (0.82, N.A.)	11	4 (36.4)	7 (63.6)	N.A. (0.76, N.A.)	1.107 (0.323, 3.792) 0.8800	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.6379
US	16	6 (37.5)	10 (62.5)	11.27 (0.99, N.A.)	17	8 (47.1)	9 (52.9)	3.09 (0.99, N.A.)	0.519 (0.155, 1.738) 0.1845	
ASIA	66	31 (47.0)	35 (53.0)	8.34 (5.62, N.A.)	51	16 (31.4)	35 (68.6)	4.60 (3.78, N.A.)	0.870 (0.452, 1.678) 0.5995	
EUROPE	124	67 (54.0)	57 (46.0)	4.83 (3.94, 10.38)	115	56 (48.7)	59 (51.3)	3.71 (2.60, 4.50)	0.805 (0.556, 1.164) 0.1431	
REST OF THE WORLD	70	40 (57.1)	30 (42.9)	5.22 (3.02, 9.76)	63	33 (52.4)	30 (47.6)	3.78 (2.43, 8.11)	0.677 (0.416, 1.103) 0.1934	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.6150
0	152	80 (52.6)	72 (47.4)	5.62 (4.24, 11.30)	132	60 (45.5)	72 (54.5)	3.88 (3.58, 4.60)	0.814 (0.572, 1.159) 0.1647	
1	122	63 (51.6)	59 (48.4)	6.24 (4.60, 9.76)	114	53 (46.5)	61 (53.5)	3.71 (2.43, N.A.)	0.656 (0.445, 0.968) 0.0410	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.5949
YES	58	31 (53.4)	27 (46.6)	4.37 (1.51, 8.34)	47	25 (53.2)	22 (46.8)	2.60 (1.41, 4.37)	0.911 (0.529, 1.567) 0.4805	
NO	218	113 (51.8)	105 (48.2)	6.54 (4.96, 11.27)	199	88 (44.2)	111 (55.8)	4.01 (3.71, 8.11)	0.710 (0.528, 0.956) 0.0186	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.5485
STAGE III	35	18 (51.4)	17 (48.6)	6.44 (2.56, N.A.)	17	6 (35.3)	11 (64.7)	3.78 (2.17, N.A.)	0.968 (0.368, 2.546) 0.8521	
STAGE IV	239	124 (51.9)	115 (48.1)	6.24 (4.57, 9.36)	228	107 (46.9)	121 (53.1)	3.78 (3.55, 4.50)	0.719 (0.547, 0.946) 0.0129	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.4281
YES	22	15 (68.2)	7 (31.8)	1.71 (0.92, 6.54)	18	12 (66.7)	6 (33.3)	2.10 (1.18, 4.01)	0.553 (0.249, 1.228) 0.5126	
NO	254	129 (50.8)	125 (49.2)	6.31 (4.96, 9.76)	228	101 (44.3)	127 (55.7)	3.88 (3.68, 7.69)	0.736 (0.558, 0.971) 0.0166	

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(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.3255
YES	80	48 (60.0)	32 (40.0)	4.37 (2.17, 5.65)	53	26 (49.1)	27 (50.9)	3.52 (2.17, N.A.)	0.975 (0.595, 1.597) 0.8334	
NO	196	96 (49.0)	100 (51.0)	7.03 (5.36, 11.27)	193	87 (45.1)	106 (54.9)	3.88 (3.68, 7.69)	0.645 (0.472, 0.880) 0.0036	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.3522
>=1%	99	43 (43.4)	56 (56.6)	9.36 (4.50, N.A.)	81	33 (40.7)	48 (59.3)	4.50 (2.43, N.A.)	0.689 (0.430, 1.104) 0.1387	
<1%/ INDETERMINATE	177	101 (57.1)	76 (42.9)	5.13 (4.30, 6.80)	165	80 (48.5)	85 (51.5)	3.78 (3.55, 4.44)	0.771 (0.564, 1.056) 0.0608	

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HR is nivolumab + SOC over SOC.
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Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Physical Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.3614
YES	60	34 (56.7)	26 (43.3)	4.34 (1.51, 5.65)	48	25 (52.1)	23 (47.9)	2.76 (1.41, 4.37)	0.964 (0.565, 1.645) 0.5883	
NO	216	110 (50.9)	106 (49.1)	6.80 (4.96, 11.27)	198	88 (44.4)	110 (55.6)	4.01 (3.71, 8.11)	0.693 (0.514, 0.935) 0.0130	

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HR is nivolumab + SOC over SOC.
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	275	150 (54.5)	125 (45.5)	5.22 (3.52, 6.93)	248	132 (53.2)	116 (46.8)	3.48 (2.27, 3.88)	0.695 (0.544, 0.888) 0.0030	
PD-L1 STATUS										0.6782
>= 1%	100	49 (49.0)	51 (51.0)	5.29 (3.48, N.A.)	82	41 (50.0)	41 (50.0)	3.55 (2.10, 6.34)	0.658 (0.428, 1.013) 0.0432	
< 1%	175	101 (57.7)	74 (42.3)	4.60 (2.79, 7.00)	166	91 (54.8)	75 (45.2)	3.48 (2.23, 4.01)	0.715 (0.530, 0.963) 0.0285	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.5659
< 65	138	73 (52.9)	65 (47.1)	5.29 (3.42, 17.51)	124	56 (45.2)	68 (54.8)	3.94 (3.48, N.A.)	0.816 (0.568, 1.173) 0.2983	
>= 65 AND < 75	108	58 (53.7)	50 (46.3)	4.76 (3.48, 9.82)	92	52 (56.5)	40 (43.5)	2.86 (2.14, 3.94)	0.621 (0.419, 0.922) 0.0129	
>= 75	29	19 (65.5)	10 (34.5)	2.40 (1.41, 6.93)	32	24 (75.0)	8 (25.0)	2.10 (0.92, 2.17)	0.565 (0.295, 1.084) 0.0776	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.5356
FEMALE	61	37 (60.7)	24 (39.3)	4.01 (2.30, 6.93)	55	34 (61.8)	21 (38.2)	2.17 (0.92, 4.21)	0.605 (0.374, 0.979) 0.0727	
MALE	214	113 (52.8)	101 (47.2)	5.42 (3.94, 9.76)	193	98 (50.8)	95 (49.2)	3.58 (2.37, 3.94)	0.720 (0.542, 0.958) 0.0154	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.9937
WHITE	192	109 (56.8)	83 (43.2)	4.47 (3.52, 5.91)	182	101 (55.5)	81 (44.5)	3.48 (2.27, 3.81)	0.670 (0.505, 0.890) 0.0053	
ASIAN	67	31 (46.3)	36 (53.7)	11.30 (2.40, N.A.)	53	25 (47.2)	28 (52.8)	3.94 (2.04, N.A.)	0.835 (0.486, 1.433) 0.4004	
OTHER	15	9 (60.0)	6 (40.0)	6.80 (0.82, N.A.)	11	6 (54.5)	5 (45.5)	2.14 (0.76, N.A.)	0.869 (0.285, 2.655) 0.7525	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.8171
US	15	6 (40.0)	9 (60.0)	N.A. (0.89, N.A.)	17	8 (47.1)	9 (52.9)	8.38 (0.99, N.A.)	1.058 (0.360, 3.112) 0.7800	
ASIA	66	31 (47.0)	35 (53.0)	11.30 (2.40, N.A.)	51	24 (47.1)	27 (52.9)	3.94 (2.04, N.A.)	0.870 (0.504, 1.503) 0.4631	
EUROPE	124	72 (58.1)	52 (41.9)	4.37 (3.48, 7.00)	116	64 (55.2)	52 (44.8)	3.58 (2.23, 3.81)	0.680 (0.477, 0.970) 0.0268	
REST OF THE WORLD	70	41 (58.6)	29 (41.4)	4.60 (2.46, 6.93)	64	36 (56.3)	28 (43.8)	3.22 (1.18, 4.01)	0.580 (0.361, 0.934) 0.0497	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.1380
0	151	85 (56.3)	66 (43.7)	5.22 (2.79, 11.30)	133	66 (49.6)	67 (50.4)	3.58 (2.46, 4.01)	0.829 (0.591, 1.164) 0.1340	
1	122	64 (52.5)	58 (47.5)	4.60 (3.48, 8.31)	115	66 (57.4)	49 (42.6)	2.23 (1.54, 4.21)	0.570 (0.399, 0.814) 0.0097	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.3658
YES	58	30 (51.7)	28 (48.3)	4.47 (1.51, N.A.)	48	31 (64.6)	17 (35.4)	1.45 (0.85, 2.46)	0.557 (0.331, 0.936) 0.0124	
NO	217	120 (55.3)	97 (44.7)	5.22 (3.52, 9.23)	200	101 (50.5)	99 (49.5)	3.75 (2.56, 4.21)	0.742 (0.562, 0.979) 0.0381	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.6232
STAGE III	35	18 (51.4)	17 (48.6)	6.44 (0.85, N.A.)	18	10 (55.6)	8 (44.4)	2.17 (0.79, N.A.)	0.729 (0.324, 1.643) 0.2858	
STAGE IV	238	131 (55.0)	107 (45.0)	4.76 (3.52, 6.93)	229	122 (53.3)	107 (46.7)	3.48 (2.27, 3.94)	0.692 (0.534, 0.896) 0.0051	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.1758
YES	22	13 (59.1)	9 (40.9)	1.68 (0.92, N.A.)	18	14 (77.8)	4 (22.2)	1.18 (0.76, 4.01)	0.423 (0.192, 0.933) 0.0538	
NO	253	137 (54.2)	116 (45.8)	5.29 (3.94, 8.31)	230	118 (51.3)	112 (48.7)	3.58 (2.40, 3.94)	0.716 (0.553, 0.928) 0.0091	

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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.5189
YES	80	53 (66.3)	27 (33.8)	2.46 (2.10, 4.21)	53	33 (62.3)	20 (37.7)	2.17 (1.54, 3.94)	0.797 (0.509, 1.246) 0.4412	
NO	195	97 (49.7)	98 (50.3)	6.80 (4.60, 13.27)	195	99 (50.8)	96 (49.2)	3.75 (2.40, 4.21)	0.628 (0.466, 0.847) 0.0010	

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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.7778
>=1%	99	48 (48.5)	51 (51.5)	5.22 (3.48, N.A.)	83	41 (49.4)	42 (50.6)	3.55 (2.10, 6.34)	0.687 (0.447, 1.058) 0.0627	
<1%/ INDETERMINATE	176	102 (58.0)	74 (42.0)	4.76 (2.79, 6.93)	165	91 (55.2)	74 (44.8)	3.48 (2.23, 4.01)	0.702 (0.521, 0.946) 0.0218	

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Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Role Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.6566
YES	60	32 (53.3)	28 (46.7)	4.47 (1.51, 6.08)	50	31 (62.0)	19 (38.0)	2.14 (0.99, 3.81)	0.614 (0.369, 1.023) 0.0332	
NO	215	118 (54.9)	97 (45.1)	5.22 (3.52, 9.23)	198	101 (51.0)	97 (49.0)	3.58 (2.40, 4.21)	0.723 (0.547, 0.955) 0.0245	

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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	90 (32.6)	186 (67.4)	N.A. (11.96, N.A.)	245	56 (22.9)	189 (77.1)	8.28 (6.01, N.A.)	0.786 (0.548, 1.127) 0.2206	
PD-L1 STATUS										0.4248
>= 1%	100	25 (25.0)	75 (75.0)	N.A.	80	15 (18.8)	65 (81.3)	N.A. (4.86, N.A.)	0.572 (0.283, 1.158) 0.1440	
< 1%	176	65 (36.9)	111 (63.1)	12.91 (9.72, N.A.)	165	41 (24.8)	124 (75.2)	8.28 (6.01, N.A.)	0.904 (0.595, 1.374) 0.6567	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.2708
< 65	139	40 (28.8)	99 (71.2)	N.A. (12.42, N.A.)	123	29 (23.6)	94 (76.4)	N.A. (6.01, N.A.)	0.543 (0.318, 0.928) 0.0379	
>= 65 AND < 75	108	38 (35.2)	70 (64.8)	N.A. (9.00, N.A.)	90	17 (18.9)	73 (81.1)	8.38 (N.A., N.A.)	1.183 (0.650, 2.152) 0.5817	
>= 75	29	12 (41.4)	17 (58.6)	9.86 (2.40, N.A.)	32	10 (31.3)	22 (68.8)	4.86 (4.07, N.A.)	0.899 (0.368, 2.196) 0.8677	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.8783
FEMALE	61	27 (44.3)	34 (55.7)	11.76 (5.36, N.A.)	55	15 (27.3)	40 (72.7)	N.A. (6.01, N.A.)	0.799 (0.398, 1.604) 0.8886	
MALE	215	63 (29.3)	152 (70.7)	N.A. (12.42, N.A.)	190	41 (21.6)	149 (78.4)	8.28 (8.28, N.A.)	0.760 (0.496, 1.163) 0.1858	

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All Randomized Subjects - Arm C and D
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EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.9393
WHITE	193	70 (36.3)	123 (63.7)	N.A. (9.23, N.A.)	179	47 (26.3)	132 (73.7)	8.28 (6.01, N.A.)	0.787 (0.530, 1.170) 0.2866	
ASIAN	67	13 (19.4)	54 (80.6)	N.A.	53	7 (13.2)	46 (86.8)	N.A. (4.60, N.A.)	0.826 (0.308, 2.215) 0.7033	
OTHER	15	6 (40.0)	9 (60.0)	11.96 (0.82, N.A.)	11	2 (18.2)	9 (81.8)	N.A. (2.04, N.A.)	1.782 (0.319, 9.964) 0.6437	

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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.9112
US	16	3 (18.8)	13 (81.3)	N.A. (0.99, N.A.)	17	2 (11.8)	15 (88.2)	8.38 (8.38, N.A.)	1.518 (0.251, 9.184) 0.5802	
ASIA	66	13 (19.7)	53 (80.3)	N.A.	51	7 (13.7)	44 (86.3)	N.A. (4.60, N.A.)	0.820 (0.305, 2.201) 0.6789	
EUROPE	124	41 (33.1)	83 (66.9)	N.A. (9.86, N.A.)	115	25 (21.7)	90 (78.3)	8.28 (4.86, N.A.)	0.809 (0.472, 1.389) 0.4441	
REST OF THE WORLD	70	33 (47.1)	37 (52.9)	9.00 (5.13, N.A.)	62	22 (35.5)	40 (64.5)	N.A. (3.48, N.A.)	0.645 (0.354, 1.173) 0.2598	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
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EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.2231
0	152	44 (28.9)	108 (71.1)	N.A. (12.91, N.A.)	131	31 (23.7)	100 (76.3)	N.A. (4.60, N.A.)	0.655 (0.394, 1.089) 0.0912	
1	122	46 (37.7)	76 (62.3)	9.76 (6.37, N.A.)	114	25 (21.9)	89 (78.1)	8.28 (8.28, N.A.)	0.970 (0.579, 1.625) 0.9194	

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HR is nivolumab + SOC over SOC.
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EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.0553
YES	58	19 (32.8)	39 (67.2)	12.91 (6.21, N.A.)	46	7 (15.2)	39 (84.8)	N.A.	1.713 (0.710, 4.137) 0.2680	
NO	218	71 (32.6)	147 (67.4)	N.A. (11.96, N.A.)	199	49 (24.6)	150 (75.4)	8.28 (6.01, N.A.)	0.657 (0.439, 0.982) 0.0537	

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EORTC QLQ-C30 Emotional Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.5235
STAGE III	35	12 (34.3)	23 (65.7)	N.A. (5.62, N.A.)	18	3 (16.7)	15 (83.3)	N.A. (2.17, N.A.)	1.346 (0.369, 4.913) 0.6542	
STAGE IV	239	77 (32.2)	162 (67.8)	N.A. (11.76, N.A.)	226	53 (23.5)	173 (76.5)	8.28 (6.01, N.A.)	0.725 (0.495, 1.061) 0.1199	

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HR is nivolumab + SOC over SOC.
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Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.2808
YES	22	7 (31.8)	15 (68.2)	12.91 (2.37, N.A.)	18	6 (33.3)	12 (66.7)	4.07 (2.10, N.A.)	0.574 (0.177, 1.866) 0.4134	
NO	254	83 (32.7)	171 (67.3)	N.A. (11.96, N.A.)	227	50 (22.0)	177 (78.0)	8.38 (6.01, N.A.)	0.808 (0.553, 1.181) 0.2939	

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Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.2465
YES	80	24 (30.0)	56 (70.0)	N.A. (12.91, N.A.)	53	8 (15.1)	45 (84.9)	8.38 (N.A., N.A.)	1.270 (0.553, 2.918) 0.5296	
NO	196	66 (33.7)	130 (66.3)	N.A. (9.82, N.A.)	192	48 (25.0)	144 (75.0)	8.28 (4.86, N.A.)	0.709 (0.472, 1.064) 0.1128	

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Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.4200
>=1%	99	24 (24.2)	75 (75.8)	N.A.	81	15 (18.5)	66 (81.5)	N.A. (4.86, N.A.)	0.588 (0.290, 1.190) 0.1653	
<1%/ INDETERMINATE	177	66 (37.3)	111 (62.7)	12.42 (9.72, N.A.)	164	41 (25.0)	123 (75.0)	8.28 (6.01, N.A.)	0.893 (0.588, 1.357) 0.6165	

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Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.0954
YES	60	20 (33.3)	40 (66.7)	12.91 (6.21, N.A.)	48	8 (16.7)	40 (83.3)	N.A.	1.563 (0.678, 3.605) 0.3352	
NO	216	70 (32.4)	146 (67.6)	N.A. (11.96, N.A.)	197	48 (24.4)	149 (75.6)	8.28 (6.01, N.A.)	0.658 (0.438, 0.988) 0.0580	

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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	146 (52.9)	130 (47.1)	5.65 (5.06, 8.54)	245	97 (39.6)	148 (60.4)	4.44 (3.78, N.A.)	0.858 (0.655, 1.125) 0.2242	
PD-L1 STATUS										0.7550
>= 1%	100	46 (46.0)	54 (54.0)	8.54 (5.19, N.A.)	80	23 (28.8)	57 (71.3)	N.A. (4.60, N.A.)	0.943 (0.558, 1.592) 0.7270	
< 1%	176	100 (56.8)	76 (43.2)	5.06 (4.17, 6.44)	165	74 (44.8)	91 (55.2)	4.17 (3.55, 5.26)	0.849 (0.617, 1.168) 0.2954	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.2834
< 65	139	76 (54.7)	63 (45.3)	5.13 (4.21, 7.00)	123	42 (34.1)	81 (65.9)	5.82 (3.78, N.A.)	1.066 (0.721, 1.577) 0.6917	
>= 65 AND < 75	108	50 (46.3)	58 (53.7)	9.76 (5.65, N.A.)	90	39 (43.3)	51 (56.7)	4.21 (2.83, N.A.)	0.668 (0.425, 1.050) 0.0443	
>= 75	29	20 (69.0)	9 (31.0)	3.84 (1.41, 6.44)	32	16 (50.0)	16 (50.0)	4.44 (1.15, N.A.)	0.886 (0.434, 1.809) 0.5359	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.6235
FEMALE	61	37 (60.7)	24 (39.3)	4.76 (2.40, 6.24)	55	24 (43.6)	31 (56.4)	4.21 (2.46, N.A.)	1.017 (0.601, 1.720) 0.8715	
MALE	215	109 (50.7)	106 (49.3)	6.08 (5.13, 9.86)	190	73 (38.4)	117 (61.6)	4.86 (3.75, N.A.)	0.808 (0.589, 1.109) 0.1385	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.1260
WHITE	193	105 (54.4)	88 (45.6)	5.13 (4.30, 6.64)	179	69 (38.5)	110 (61.5)	4.86 (3.94, N.A.)	0.991 (0.722, 1.358) 0.9527	
ASIAN	67	31 (46.3)	36 (53.7)	9.30 (5.13, 12.78)	53	26 (49.1)	27 (50.9)	3.55 (2.20, N.A.)	0.474 (0.263, 0.855) 0.0038	
OTHER	15	9 (60.0)	6 (40.0)	5.65 (0.82, N.A.)	11	2 (18.2)	9 (81.8)	N.A. (0.76, N.A.)	1.967 (0.389, 9.956) 0.4350	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.2989
US	16	5 (31.3)	11 (68.8)	N.A. (2.14, N.A.)	17	5 (29.4)	12 (70.6)	4.44 (3.09, N.A.)	0.877 (0.236, 3.254) 0.8319	
ASIA	66	31 (47.0)	35 (53.0)	9.30 (5.13, 12.78)	51	26 (51.0)	25 (49.0)	3.55 (2.20, N.A.)	0.480 (0.266, 0.865) 0.0032	
EUROPE	124	71 (57.3)	53 (42.7)	5.16 (3.48, 6.44)	115	42 (36.5)	73 (63.5)	4.86 (3.94, N.A.)	1.082 (0.727, 1.613) 0.6583	
REST OF THE WORLD	70	39 (55.7)	31 (44.3)	5.06 (4.21, 9.46)	62	24 (38.7)	38 (61.3)	N.A. (2.46, N.A.)	0.911 (0.536, 1.547) 0.6974	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.1584
0	152	77 (50.7)	75 (49.3)	6.28 (4.76, 11.30)	131	58 (44.3)	73 (55.7)	3.94 (2.86, N.A.)	0.748 (0.520, 1.076) 0.0820	
1	122	69 (56.6)	53 (43.4)	5.19 (4.30, 6.44)	114	39 (34.2)	75 (65.8)	5.26 (4.21, N.A.)	1.007 (0.668, 1.520) 0.7878	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.8080
YES	58	26 (44.8)	32 (55.2)	6.24 (4.99, N.A.)	46	17 (37.0)	29 (63.0)	N.A. (2.46, N.A.)	0.811 (0.433, 1.519) 0.6250	
NO	218	120 (55.0)	98 (45.0)	5.65 (4.53, 9.13)	199	80 (40.2)	119 (59.8)	4.44 (3.78, 5.82)	0.863 (0.638, 1.166) 0.2615	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.4118
STAGE III	35	20 (57.1)	15 (42.9)	5.16 (2.83, 9.30)	18	6 (33.3)	12 (66.7)	N.A. (1.51, N.A.)	1.195 (0.473, 3.018) 0.8220	
STAGE IV	239	124 (51.9)	115 (48.1)	5.95 (5.06, 9.76)	226	91 (40.3)	135 (59.7)	4.44 (3.78, 5.82)	0.817 (0.613, 1.089) 0.1459	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.3310
YES	22	10 (45.5)	12 (54.5)	5.65 (0.95, N.A.)	18	8 (44.4)	10 (55.6)	4.21 (1.02, N.A.)	0.568 (0.211, 1.531) 0.3854	
NO	254	136 (53.5)	118 (46.5)	5.95 (5.06, 9.13)	227	89 (39.2)	138 (60.8)	4.60 (3.78, N.A.)	0.882 (0.665, 1.170) 0.3075	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.9934
YES	80	42 (52.5)	38 (47.5)	5.16 (4.21, 11.30)	53	22 (41.5)	31 (58.5)	4.44 (3.09, N.A.)	0.871 (0.509, 1.491) 0.6659	
NO	196	104 (53.1)	92 (46.9)	6.08 (4.99, 9.30)	192	75 (39.1)	117 (60.9)	4.60 (3.78, N.A.)	0.852 (0.622, 1.168) 0.2580	

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HR is nivolumab + SOC over SOC.
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.7420
>=1%	99	45 (45.5)	54 (54.5)	9.46 (5.22, N.A.)	81	23 (28.4)	58 (71.6)	N.A. (4.60, N.A.)	0.950 (0.561, 1.608) 0.7417	
<1%/ INDETERMINATE	177	101 (57.1)	76 (42.9)	4.99 (4.17, 6.44)	164	74 (45.1)	90 (54.9)	3.94 (3.55, 5.26)	0.844 (0.614, 1.160) 0.2765	

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HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Cognitive Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.8774
YES	60	27 (45.0)	33 (55.0)	6.24 (4.99, N.A.)	48	17 (35.4)	31 (64.6)	N.A. (2.46, N.A.)	0.835 (0.448, 1.556) 0.6293	
NO	216	119 (55.1)	97 (44.9)	5.65 (4.53, 8.54)	197	80 (40.6)	117 (59.4)	4.44 (3.78, 5.82)	0.858 (0.634, 1.160) 0.2607	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
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Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	146 (52.9)	130 (47.1)	4.99 (3.88, 7.79)	245	103 (42.0)	142 (58.0)	4.21 (3.68, N.A.)	0.962 (0.743, 1.247) 0.9988	
PD-L1 STATUS										0.9297
>= 1%	100	48 (48.0)	52 (52.0)	5.36 (2.76, N.A.)	80	32 (40.0)	48 (60.0)	N.A. (2.30, N.A.)	1.004 (0.638, 1.581) 0.9266	
< 1%	176	98 (55.7)	78 (44.3)	4.53 (2.89, 7.00)	165	71 (43.0)	94 (57.0)	4.17 (3.55, N.A.)	0.943 (0.686, 1.296) 0.9491	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.6296
< 65	139	71 (51.1)	68 (48.9)	4.99 (3.35, N.A.)	123	45 (36.6)	78 (63.4)	N.A. (3.71, N.A.)	1.127 (0.771, 1.649) 0.3908	
>= 65 AND < 75	108	60 (55.6)	48 (44.4)	4.99 (2.79, 10.18)	90	41 (45.6)	49 (54.4)	3.55 (2.23, N.A.)	0.848 (0.561, 1.282) 0.6028	
>= 75	29	15 (51.7)	14 (48.3)	4.44 (1.68, N.A.)	32	17 (53.1)	15 (46.9)	3.88 (2.10, 4.21)	0.845 (0.410, 1.742) 0.4378	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.7654
FEMALE	61	32 (52.5)	29 (47.5)	4.44 (2.66, N.A.)	55	25 (45.5)	30 (54.5)	4.17 (2.23, N.A.)	0.923 (0.540, 1.576) 0.8541	
MALE	215	114 (53.0)	101 (47.0)	4.99 (3.78, 7.79)	190	78 (41.1)	112 (58.9)	4.21 (3.71, N.A.)	0.972 (0.722, 1.308) 0.9400	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.9434
WHITE	193	106 (54.9)	87 (45.1)	4.47 (2.89, 5.68)	179	82 (45.8)	97 (54.2)	4.07 (3.48, N.A.)	0.945 (0.703, 1.270) 0.7914	
ASIAN	67	30 (44.8)	37 (55.2)	N.A. (2.40, N.A.)	53	16 (30.2)	37 (69.8)	N.A. (3.55, N.A.)	1.129 (0.607, 2.098) 0.4190	
OTHER	15	9 (60.0)	6 (40.0)	5.36 (0.82, N.A.)	11	5 (45.5)	6 (54.5)	2.37 (0.76, N.A.)	0.685 (0.208, 2.260) 0.5553	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.9854
US	16	6 (37.5)	10 (62.5)	N.A. (0.99, N.A.)	17	8 (47.1)	9 (52.9)	6.05 (1.51, N.A.)	0.961 (0.332, 2.785) 0.7905	
ASIA	66	30 (45.5)	36 (54.5)	N.A. (2.40, N.A.)	51	16 (31.4)	35 (68.6)	N.A. (2.63, N.A.)	1.141 (0.614, 2.120) 0.4556	
EUROPE	124	72 (58.1)	52 (41.9)	4.47 (2.89, 7.00)	115	50 (43.5)	65 (56.5)	4.21 (2.40, N.A.)	0.949 (0.653, 1.380) 0.9619	
REST OF THE WORLD	70	38 (54.3)	32 (45.7)	4.37 (2.27, N.A.)	62	29 (46.8)	33 (53.2)	4.07 (2.46, N.A.)	0.939 (0.574, 1.536) 0.8071	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.1614
0	152	78 (51.3)	74 (48.7)	5.16 (3.55, N.A.)	131	46 (35.1)	85 (64.9)	N.A. (3.88, N.A.)	1.214 (0.835, 1.765) 0.3207	
1	122	68 (55.7)	54 (44.3)	4.37 (2.56, 5.49)	114	57 (50.0)	57 (50.0)	3.68 (2.17, 8.38)	0.752 (0.525, 1.078) 0.4575	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.7727
YES	58	30 (51.7)	28 (48.3)	4.44 (2.14, N.A.)	46	24 (52.2)	22 (47.8)	2.46 (2.14, N.A.)	0.904 (0.526, 1.554) 0.5293	
NO	218	116 (53.2)	102 (46.8)	5.13 (3.78, 10.18)	199	79 (39.7)	120 (60.3)	8.38 (3.88, N.A.)	0.975 (0.725, 1.312) 0.7847	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.3749
STAGE III	35	20 (57.1)	15 (42.9)	4.40 (2.17, N.A.)	18	7 (38.9)	11 (61.1)	4.21 (1.51, N.A.)	1.286 (0.533, 3.102) 0.7380	
STAGE IV	239	125 (52.3)	114 (47.7)	4.99 (3.88, 10.18)	226	96 (42.5)	130 (57.5)	4.17 (3.55, N.A.)	0.921 (0.700, 1.211) 0.8682	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.0909
YES	22	10 (45.5)	12 (54.5)	10.18 (1.02, N.A.)	18	12 (66.7)	6 (33.3)	2.10 (0.76, 3.55)	0.410 (0.166, 1.016) 0.0304	
NO	254	136 (53.5)	118 (46.5)	4.93 (3.55, 7.79)	227	91 (40.1)	136 (59.9)	8.38 (3.88, N.A.)	1.026 (0.781, 1.348) 0.5761	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.6002
YES	80	41 (51.3)	39 (48.8)	4.93 (2.40, N.A.)	53	19 (35.8)	34 (64.2)	8.38 (3.71, N.A.)	1.147 (0.657, 2.004) 0.3428	
NO	196	105 (53.6)	91 (46.4)	4.99 (3.55, 10.18)	192	84 (43.8)	108 (56.3)	4.07 (3.22, N.A.)	0.927 (0.689, 1.246) 0.6257	

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(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.9952
>=1%	99	47 (47.5)	52 (52.5)	5.36 (3.35, N.A.)	81	32 (39.5)	49 (60.5)	N.A. (2.37, N.A.)	1.024 (0.648, 1.616) 0.9445	
<1%/ INDETERMINATE	177	99 (55.9)	78 (44.1)	4.47 (2.79, 7.00)	164	71 (43.3)	93 (56.7)	4.17 (3.55, N.A.)	0.935 (0.681, 1.284) 0.9563	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTC QLQ-C30 Social Functioning (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.9766
YES	60	33 (55.0)	27 (45.0)	4.24 (1.54, 5.29)	48	25 (52.1)	23 (47.9)	2.69 (2.17, N.A.)	0.974 (0.577, 1.646) 0.7180	
NO	216	113 (52.3)	103 (47.7)	5.16 (4.24, 12.48)	197	78 (39.6)	119 (60.4)	8.38 (3.88, N.A.)	0.954 (0.707, 1.286) 0.8952	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
OVERALL	276	141 (51.1)	135 (48.9)	6.14 (4.53, 9.99)	245	104 (42.4)	141 (57.6)	4.37 (3.81, 6.34)	0.961 (0.739, 1.250) 0.2894	
PD-L1 STATUS										0.3687
>= 1%	100	46 (46.0)	54 (54.0)	7.69 (4.50, N.A.)	80	31 (38.8)	49 (61.3)	4.70 (3.22, N.A.)	0.820 (0.513, 1.310) 0.3607	
< 1%	176	95 (54.0)	81 (46.0)	6.05 (3.42, 10.02)	165	73 (44.2)	92 (55.8)	4.21 (3.75, 7.16)	1.069 (0.777, 1.471) 0.5730	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
AGE CATEGORIZATION										0.1507
< 65	139	74 (53.2)	65 (46.8)	6.54 (4.53, 11.27)	123	47 (38.2)	76 (61.8)	4.50 (3.81, N.A.)	0.960 (0.654, 1.408) 0.6279	
>= 65 AND < 75	108	45 (41.7)	63 (58.3)	N.A. (5.29, N.A.)	90	39 (43.3)	51 (56.7)	4.21 (3.52, 7.69)	0.810 (0.519, 1.266) 0.1299	
>= 75	29	22 (75.9)	7 (24.1)	2.07 (0.95, 2.40)	32	18 (56.3)	14 (43.8)	2.63 (1.61, N.A.)	1.844 (0.974, 3.490) 0.2152	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
SEX										0.9517
FEMALE	61	36 (59.0)	25 (41.0)	4.01 (2.33, 10.02)	55	26 (47.3)	29 (52.7)	3.84 (2.27, N.A.)	0.973 (0.582, 1.626) 0.8897	
MALE	215	105 (48.8)	110 (51.2)	7.13 (5.36, 12.19)	190	78 (41.1)	112 (58.9)	4.37 (3.81, 7.16)	0.962 (0.707, 1.308) 0.2532	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
RACE										0.9505
WHITE	193	100 (51.8)	93 (48.2)	6.14 (4.01, 10.02)	179	78 (43.6)	101 (56.4)	4.21 (3.75, 6.34)	0.961 (0.707, 1.307) 0.2849	
ASIAN	67	33 (49.3)	34 (50.7)	7.69 (2.40, N.A.)	53	22 (41.5)	31 (58.5)	4.60 (2.30, N.A.)	0.915 (0.519, 1.611) 0.7686	
OTHER	15	8 (53.3)	7 (46.7)	6.08 (1.18, N.A.)	11	4 (36.4)	7 (63.6)	N.A. (0.76, N.A.)	1.457 (0.332, 6.393) 0.9529	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
REGION										0.3239
US	16	5 (31.3)	11 (68.8)	N.A. (1.02, N.A.)	17	9 (52.9)	8 (47.1)	3.45 (1.51, N.A.)	0.425 (0.138, 1.310) 0.2050	
ASIA	66	33 (50.0)	33 (50.0)	6.11 (2.27, N.A.)	51	22 (43.1)	29 (56.9)	4.60 (2.23, N.A.)	0.914 (0.519, 1.610) 0.7223	
EUROPE	124	69 (55.6)	55 (44.4)	5.36 (3.48, 9.99)	115	49 (42.6)	66 (57.4)	4.40 (3.75, 7.16)	1.079 (0.736, 1.581) 0.5605	
REST OF THE WORLD	70	34 (48.6)	36 (51.4)	7.13 (2.79, N.A.)	62	24 (38.7)	38 (61.3)	3.94 (3.52, N.A.)	1.052 (0.615, 1.800) 0.7740	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
BASELINE ECOG PERFORMANCE STATUS										0.0410*
0	152	84 (55.3)	68 (44.7)	5.36 (2.79, 9.79)	131	56 (42.7)	75 (57.3)	4.21 (3.58, 7.69)	1.189 (0.836, 1.692) 0.9323	
1	122	56 (45.9)	66 (54.1)	9.49 (4.53, N.A.)	114	48 (42.1)	66 (57.9)	4.40 (3.22, 7.16)	0.714 (0.480, 1.061) 0.1493	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Table 11.1
Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS										0.8211
YES	58	27 (46.6)	31 (53.4)	6.08 (3.98, N.A.)	46	20 (43.5)	26 (56.5)	4.40 (2.23, 7.16)	0.813 (0.450, 1.469) 0.3263	
NO	218	114 (52.3)	104 (47.7)	6.14 (4.17, 11.27)	199	84 (42.2)	115 (57.8)	4.37 (3.58, 7.69)	0.993 (0.741, 1.330) 0.4938	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
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Subgroup analyses of Time to First Deterioration EORTC QLQ-C30
All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
DISEASE STAGE AT STUDY ENTRY										0.7722
STAGE III	35	16 (45.7)	19 (54.3)	12.19 (2.17, N.A.)	18	9 (50.0)	9 (50.0)	3.45 (1.51, N.A.)	1.120 (0.476, 2.638) 0.4973	
STAGE IV	239	123 (51.5)	116 (48.5)	6.11 (4.53, 9.79)	226	94 (41.6)	132 (58.4)	4.40 (3.84, 7.16)	0.945 (0.715, 1.249) 0.3258	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
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Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR RADIOTHERAPY										0.6786
YES	22	15 (68.2)	7 (31.8)	1.87 (0.89, 7.66)	18	6 (33.3)	12 (66.7)	N.A. (1.48, N.A.)	1.235 (0.453, 3.366) 0.2281	
NO	254	126 (49.6)	128 (50.4)	7.13 (4.86, 12.19)	227	98 (43.2)	129 (56.8)	4.37 (3.81, 6.34)	0.928 (0.705, 1.222) 0.1345	

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HR is nivolumab + SOC over SOC.
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Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PRIOR SYSTEMIC CANCER THERAPY										0.2836
YES	80	44 (55.0)	36 (45.0)	4.17 (2.37, N.A.)	53	24 (45.3)	29 (54.7)	4.50 (3.09, 7.69)	1.292 (0.775, 2.153) 0.6549	
NO	196	97 (49.5)	99 (50.5)	7.69 (5.13, 12.19)	192	80 (41.7)	112 (58.3)	4.21 (3.75, 7.16)	0.850 (0.623, 1.158) 0.1052	

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Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
PD-L1 STATUS (IRT)										0.3207
>=1%	99	45 (45.5)	54 (54.5)	7.69 (5.13, N.A.)	81	32 (39.5)	49 (60.5)	4.70 (3.22, N.A.)	0.794 (0.497, 1.267) 0.2705	
<1%/ INDETERMINATE	177	96 (54.2)	81 (45.8)	6.05 (2.89, 9.99)	164	72 (43.9)	92 (56.1)	4.21 (3.75, 7.16)	1.078 (0.783, 1.483) 0.6527	

June 2023 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. N.M.E. = Not meaningful estimate; N.E. = Not estimable.
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All Randomized Subjects - Arm C and D
Only Subjects with a Non-Missing Baseline and >=1 Non-Missing Post-Baseline Value of the PRO Score

EORTCC QLQ-C30 Global Health Status (MID = 10)	Nivolumab + SOC				SOC				Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	N	Subjects with event n (%)	Censored subjects n (%)	KME [95%CI] (mon) (1)	HR [95%CI] p-value (2) (3)	Test for Interaction p-value (4) (5)
LIVER METASTASIS (IRT)										0.8384
YES	60	29 (48.3)	31 (51.7)	6.08 (3.98, N.A.)	48	21 (43.8)	27 (56.3)	3.84 (2.60, 7.16)	0.817 (0.460, 1.451) 0.3382	
NO	216	112 (51.9)	104 (48.1)	6.54 (4.17, 11.27)	197	83 (42.1)	114 (57.9)	4.37 (3.75, N.A.)	0.995 (0.741, 1.337) 0.4965	

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(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate.
HR is nivolumab + SOC over SOC.
(3) Unstratified Log-rank test (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) p-value of <0.05 is indicated by 1 asterisk (indicates potential effect modification).
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-sy-tfdsub-ebr2114.sas 09APR2024:11:45:43

Anhang 4-G-1.4.1.5: Subgruppenanalysen für die Endpunkte zur Verträglichkeit

Anhang 4-G-1.4.1.5.1: Subgruppenanalysen für jegliche UE

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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	303 (99.7)	0.13 (0.10, 0.16)	288	285 (99.0)	0.13 (0.10, 0.20)	1.001 (0.851, 1.177) 0.9886	
PD-L1 STATUS								0.5470
>= 1%	112	111 (99.1)	0.11 (0.10, 0.16)	100	99 (99.0)	0.10 (0.07, 0.16)	0.936 (0.712, 1.232) 0.5619	
< 1%	192	192 (100.0)	0.16 (0.13, 0.23)	188	186 (98.9)	0.16 (0.10, 0.23)	1.027 (0.839, 1.257) 0.8024	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:07

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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.8916
< 65	150	149 (99.3)	0.13 (0.10, 0.16)	140	138 (98.6)	0.13 (0.10, 0.20)	1.022 (0.810, 1.289) 0.8690	
>= 65 AND < 75	120	120 (100.0)	0.13 (0.10, 0.23)	111	110 (99.1)	0.10 (0.07, 0.20)	0.950 (0.732, 1.234) 0.6724	
>= 75	34	34 (100.0)	0.21 (0.10, 0.26)	37	37 (100.0)	0.20 (0.13, 0.30)	1.088 (0.677, 1.747) 0.7276	
SEX								0.8065
FEMALE	68	68 (100.0)	0.10 (0.07, 0.16)	65	65 (100.0)	0.10 (0.07, 0.20)	1.029 (0.730, 1.450) 0.8780	
MALE	236	235 (99.6)	0.16 (0.13, 0.23)	223	220 (98.7)	0.13 (0.10, 0.20)	0.996 (0.828, 1.197) 0.9424	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:07

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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9392
WHITE	211	211 (100.0)	0.20 (0.13, 0.23)	214	211 (98.6)	0.16 (0.13, 0.23)	0.988 (0.816, 1.197) 0.8697	
ASIAN	75	74 (98.7)	0.10 (0.07, 0.13)	59	59 (100.0)	0.10 (0.07, 0.13)	0.944 (0.667, 1.338) 0.7163	
OTHER	17	17 (100.0)	0.10 (0.03, 0.23)	12	12 (100.0)	0.08 (0.03, 0.46)	0.929 (0.431, 2.002) 0.8767	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:07

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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9571
US	19	19 (100.0)	0.07 (0.03, 0.23)	20	20 (100.0)	0.07 (0.03, 0.13)	1.122 (0.588, 2.140) 0.8558	
ASIA	72	71 (98.6)	0.10 (0.07, 0.13)	57	57 (100.0)	0.10 (0.07, 0.13)	0.958 (0.672, 1.367) 0.7838	
EUROPE	134	134 (100.0)	0.23 (0.13, 0.26)	134	131 (97.8)	0.21 (0.13, 0.26)	0.976 (0.766, 1.244) 0.8016	
REST OF THE WORLD	79	79 (100.0)	0.16 (0.10, 0.23)	77	77 (100.0)	0.13 (0.10, 0.20)	1.038 (0.755, 1.427) 0.8293	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:07

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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.6937
0	162	162 (100.0)	0.13 (0.10, 0.20)	155	153 (98.7)	0.13 (0.10, 0.23)	1.024 (0.820, 1.278) 0.8614	
1	140	139 (99.3)	0.16 (0.10, 0.23)	133	132 (99.2)	0.13 (0.10, 0.20)	0.941 (0.740, 1.195) 0.6198	
LIVER METASTASIS								0.6543
YES	62	62 (100.0)	0.13 (0.10, 0.23)	59	58 (98.3)	0.16 (0.10, 0.26)	1.066 (0.744, 1.527) 0.7592	
NO	242	241 (99.6)	0.13 (0.10, 0.16)	229	227 (99.1)	0.13 (0.10, 0.20)	0.981 (0.818, 1.177) 0.8118	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7018
STAGE III	37	37 (100.0)	0.16 (0.07, 0.26)	24	24 (100.0)	0.21 (0.07, 0.30)	0.918 (0.546, 1.543) 0.7256	
STAGE IV	265	264 (99.6)	0.13 (0.10, 0.16)	262	259 (98.9)	0.13 (0.10, 0.16)	1.027 (0.865, 1.220) 0.7787	
PRIOR RADIOTHERAPY								0.4646
YES	26	26 (100.0)	0.18 (0.07, 0.26)	22	22 (100.0)	0.15 (0.07, 0.46)	1.313 (0.730, 2.364) 0.3883	
NO	278	277 (99.6)	0.13 (0.10, 0.16)	266	263 (98.9)	0.13 (0.10, 0.20)	0.984 (0.831, 1.165) 0.8492	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:07

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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.3335
YES	88	87 (98.9)	0.10 (0.07, 0.16)	61	60 (98.4)	0.07 (0.07, 0.13)	1.106 (0.793, 1.543) 0.5204	
NO	216	216 (100.0)	0.16 (0.13, 0.23)	227	225 (99.1)	0.16 (0.13, 0.20)	0.946 (0.784, 1.141) 0.5462	
PD-L1 STATUS (IRT)								0.4713
>=1%	111	110 (99.1)	0.13 (0.10, 0.23)	101	100 (99.0)	0.10 (0.07, 0.13)	0.925 (0.703, 1.217) 0.5067	
<1%/INDETERMINATE	193	193 (100.0)	0.16 (0.13, 0.20)	187	185 (98.9)	0.16 (0.10, 0.23)	1.035 (0.846, 1.267) 0.7452	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.1
Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.6141
YES	64	64 (100.0)	0.13 (0.10, 0.23)	61	60 (98.4)	0.16 (0.10, 0.26)	1.076 (0.756, 1.533) 0.6990	
NO	240	239 (99.6)	0.13 (0.10, 0.16)	227	225 (99.1)	0.13 (0.10, 0.16)	0.979 (0.815, 1.175) 0.7833	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:07

Anhang 4-G-1.4.1.5.2: Subgruppenanalysen für schwere UE

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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	238 (78.3)	2.07 (1.61, 2.33)	288	196 (68.1)	2.43 (1.91, 3.02)	1.156 (0.955, 1.399) 0.1400	
PD-L1 STATUS								0.5776
>= 1%	112	90 (80.4)	1.64 (0.92, 2.33)	100	69 (69.0)	2.43 (1.48, 3.06)	1.258 (0.917, 1.725) 0.1581	
< 1%	192	148 (77.1)	2.12 (1.61, 2.89)	188	127 (67.6)	2.40 (1.81, 3.19)	1.100 (0.865, 1.399) 0.4399	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:10

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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.4086
< 65	150	114 (76.0)	2.89 (2.10, 3.25)	140	92 (65.7)	2.66 (1.91, 3.35)	1.053 (0.797, 1.392) 0.7185	
>= 65 AND < 75	120	92 (76.7)	1.36 (0.72, 2.27)	111	76 (68.5)	2.20 (1.22, 3.02)	1.199 (0.882, 1.630) 0.2539	
>= 75	34	32 (94.1)	0.92 (0.59, 2.04)	37	28 (75.7)	2.14 (0.76, 3.55)	1.690 (1.009, 2.831) 0.0439	
SEX								0.1493
FEMALE	68	55 (80.9)	0.79 (0.69, 1.64)	65	43 (66.2)	2.53 (1.18, 3.84)	1.501 (1.003, 2.246) 0.0477	
MALE	236	183 (77.5)	2.30 (1.77, 3.06)	223	153 (68.6)	2.40 (1.91, 3.02)	1.071 (0.862, 1.331) 0.5405	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.3235
WHITE	211	167 (79.1)	2.07 (1.51, 2.40)	214	142 (66.4)	2.66 (2.04, 3.22)	1.258 (1.004, 1.577) 0.0472	
ASIAN	75	57 (76.0)	2.27 (0.76, 3.19)	59	43 (72.9)	1.87 (0.59, 3.02)	0.850 (0.567, 1.274) 0.4277	
OTHER	17	14 (82.4)	1.41 (0.26, 3.09)	12	9 (75.0)	3.40 (0.62, N.A.)	1.383 (0.587, 3.257) 0.4582	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:10

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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5415
US	19	16 (84.2)	0.72 (0.46, 2.56)	20	15 (75.0)	1.53 (0.26, 4.86)	1.300 (0.639, 2.645) 0.5198	
ASIA	72	54 (75.0)	2.27 (0.72, 3.25)	57	41 (71.9)	1.87 (0.59, 3.06)	0.850 (0.561, 1.288) 0.4407	
EUROPE	134	105 (78.4)	2.14 (1.77, 3.12)	134	85 (63.4)	2.99 (2.30, 3.78)	1.292 (0.967, 1.726) 0.0830	
REST OF THE WORLD	79	63 (79.7)	1.64 (0.76, 2.43)	77	55 (71.4)	2.10 (1.48, 3.06)	1.207 (0.838, 1.737) 0.3178	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.4817
0	162	125 (77.2)	2.17 (1.64, 3.09)	155	99 (63.9)	2.92 (2.07, 3.68)	1.212 (0.927, 1.584) 0.1587	
1	140	111 (79.3)	1.77 (0.89, 2.43)	133	97 (72.9)	2.04 (1.05, 2.76)	1.072 (0.814, 1.411) 0.6297	
LIVER METASTASIS								0.0767
YES	62	53 (85.5)	0.72 (0.59, 1.84)	59	41 (69.5)	2.56 (0.99, 3.91)	1.593 (1.055, 2.406) 0.0261	
NO	242	185 (76.4)	2.30 (1.64, 3.06)	229	155 (67.7)	2.40 (1.91, 3.02)	1.068 (0.861, 1.326) 0.5554	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9552
STAGE III	37	26 (70.3)	2.76 (0.95, 7.85)	24	15 (62.5)	3.02 (2.33, N.A.)	1.118 (0.584, 2.143) 0.7470	
STAGE IV	265	211 (79.6)	2.00 (1.41, 2.30)	262	179 (68.3)	2.30 (1.77, 2.99)	1.182 (0.967, 1.446) 0.1049	
PRIOR RADIOTHERAPY								0.1299
YES	26	23 (88.5)	0.57 (0.36, 0.72)	22	17 (77.3)	1.30 (0.76, 2.66)	1.980 (1.047, 3.744) 0.0331	
NO	278	215 (77.3)	2.27 (1.71, 2.92)	266	179 (67.3)	2.63 (1.97, 3.06)	1.113 (0.911, 1.361) 0.2992	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.8412
YES	88	69 (78.4)	1.64 (0.76, 2.30)	61	43 (70.5)	2.30 (0.82, 3.48)	1.124 (0.765, 1.651) 0.5508	
NO	216	169 (78.2)	2.27 (1.61, 3.02)	227	153 (67.4)	2.56 (1.94, 3.02)	1.153 (0.924, 1.439) 0.2124	
PD-L1 STATUS (IRT)								0.6220
>=1%	111	89 (80.2)	1.64 (0.92, 2.33)	101	70 (69.3)	2.43 (1.54, 3.02)	1.249 (0.911, 1.712) 0.1720	
<1%/INDETERMINATE	193	149 (77.2)	2.10 (1.64, 2.76)	187	126 (67.4)	2.40 (1.77, 3.19)	1.106 (0.869, 1.407) 0.4153	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.0140*
YES	64	56 (87.5)	0.72 (0.49, 1.51)	61	41 (67.2)	2.56 (1.12, 4.04)	1.798 (1.196, 2.704) 0.0044	
NO	240	182 (75.8)	2.30 (1.77, 3.09)	227	155 (68.3)	2.40 (1.91, 3.02)	1.032 (0.831, 1.282) 0.7814	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Anhang 4-G-1.4.1.5.3: Subgruppenanalysen für schwerwiegende UE

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Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	147 (48.4)	17.25 (8.80, 24.15)	288	115 (39.9)	N.A. (8.71, N.A.)	0.913 (0.707, 1.179) 0.4853	
PD-L1 STATUS								0.6678
>= 1%	112	54 (48.2)	13.77 (7.20, N.A.)	100	42 (42.0)	N.A. (3.48, N.A.)	0.918 (0.604, 1.394) 0.6880	
< 1%	192	93 (48.4)	17.25 (8.77, 24.15)	188	73 (38.8)	8.71 (7.69, N.A.)	0.902 (0.652, 1.247) 0.5309	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.8531
< 65	150	72 (48.0)	17.48 (8.38, 25.72)	140	50 (35.7)	N.A.	0.989 (0.677, 1.445) 0.9565	
>= 65 AND < 75	120	53 (44.2)	17.48 (8.57, N.A.)	111	43 (38.7)	8.71 (7.69, N.A.)	0.855 (0.561, 1.305) 0.4650	
>= 75	34	22 (64.7)	3.96 (0.85, 20.17)	37	22 (59.5)	3.35 (1.87, N.A.)	0.900 (0.486, 1.668) 0.7350	
SEX								0.3366
FEMALE	68	36 (52.9)	8.57 (5.62, N.A.)	65	24 (36.9)	N.A. (3.81, N.A.)	1.135 (0.662, 1.946) 0.6478	
MALE	236	111 (47.0)	17.48 (10.18, 25.17)	223	91 (40.8)	8.71 (7.69, N.A.)	0.859 (0.642, 1.149) 0.3057	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.3435
WHITE	211	107 (50.7)	17.25 (7.85, 25.17)	214	82 (38.3)	N.A. (8.71, N.A.)	1.092 (0.810, 1.474) 0.5637	
ASIAN	75	32 (42.7)	13.77 (8.25, N.A.)	59	25 (42.4)	N.A. (3.42, N.A.)	0.566 (0.320, 1.003) 0.0485	
OTHER	17	8 (47.1)	24.15 (2.60, N.A.)	12	6 (50.0)	5.16 (0.62, N.A.)	0.558 (0.177, 1.756) 0.3116	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.7827
US	19	12 (63.2)	8.51 (0.69, N.A.)	20	12 (60.0)	5.45 (0.95, N.A.)	0.822 (0.357, 1.895) 0.6457	
ASIA	72	30 (41.7)	13.77 (8.38, N.A.)	57	23 (40.4)	N.A. (3.48, N.A.)	0.562 (0.309, 1.022) 0.0558	
EUROPE	134	72 (53.7)	10.45 (7.20, 24.15)	134	52 (38.8)	N.A.	1.067 (0.734, 1.549) 0.7342	
REST OF THE WORLD	79	33 (41.8)	N.A. (7.26, N.A.)	77	28 (36.4)	N.A.	1.075 (0.643, 1.797) 0.7867	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.4749
0	162	81 (50.0)	17.48 (8.80, 25.17)	155	57 (36.8)	N.A.	0.974 (0.681, 1.395) 0.8866	
1	140	64 (45.7)	17.48 (8.05, N.A.)	133	58 (43.6)	8.71 (4.30, N.A.)	0.846 (0.585, 1.223) 0.3731	
LIVER METASTASIS								0.1307
YES	62	35 (56.5)	5.62 (2.10, N.A.)	59	24 (40.7)	N.A. (4.34, N.A.)	1.421 (0.841, 2.401) 0.1882	
NO	242	112 (46.3)	19.22 (11.10, 25.72)	229	91 (39.7)	8.71 (8.71, N.A.)	0.790 (0.588, 1.062) 0.1169	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.4638
STAGE III	37	17 (45.9)	17.48 (7.85, N.A.)	24	11 (45.8)	N.A. (1.45, N.A.)	0.670 (0.295, 1.521) 0.3355	
STAGE IV	265	130 (49.1)	14.29 (8.38, 24.15)	262	103 (39.3)	N.A. (8.71, N.A.)	0.960 (0.732, 1.257) 0.7656	
PRIOR RADIOTHERAPY								0.8019
YES	26	14 (53.8)	6.14 (0.69, N.A.)	22	12 (54.5)	3.04 (1.15, N.A.)	0.943 (0.429, 2.073) 0.8840	
NO	278	133 (47.8)	17.48 (10.18, 25.17)	266	103 (38.7)	N.A. (8.71, N.A.)	0.911 (0.695, 1.194) 0.5004	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:12

Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.5084
YES	88	44 (50.0)	13.77 (7.89, 25.17)	61	22 (36.1)	8.71 (7.69, N.A.)	0.922 (0.534, 1.595) 0.7724	
NO	216	103 (47.7)	17.25 (8.77, 25.72)	227	93 (41.0)	N.A.	0.911 (0.680, 1.220) 0.5296	
PD-L1 STATUS (IRT)								0.6885
>=1%	111	54 (48.6)	13.77 (7.20, N.A.)	101	43 (42.6)	N.A. (3.48, N.A.)	0.917 (0.605, 1.389) 0.6807	
<1%/INDETERMINATE	193	93 (48.2)	17.25 (8.77, 24.15)	187	72 (38.5)	N.A. (7.69, N.A.)	0.903 (0.652, 1.250) 0.5375	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.0616
YES	64	38 (59.4)	2.92 (1.48, 17.48)	61	25 (41.0)	N.A. (4.34, N.A.)	1.538 (0.924, 2.560) 0.0967	
NO	240	109 (45.4)	20.04 (11.70, 25.72)	227	90 (39.6)	8.71 (8.71, N.A.)	0.764 (0.567, 1.030) 0.0767	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:12

Anhang 4-G-1.4.1.5.4: Subgruppenanalysen für zum Therapieabbruch führende UE

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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	94 (30.9)	N.A.	288	67 (23.3)	N.A.	1.090 (0.788, 1.509) 0.6015	
PD-L1 STATUS								0.4949
>= 1%	112	34 (30.4)	N.A.	100	25 (25.0)	N.A.	0.944 (0.551, 1.618) 0.8337	
< 1%	192	60 (31.3)	N.A. (22.80, N.A.)	188	42 (22.3)	N.A.	1.185 (0.789, 1.780) 0.4127	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.4673
< 65	150	43 (28.7)	N.A.	140	26 (18.6)	N.A.	1.295 (0.781, 2.147) 0.3157	
>= 65 AND < 75	120	39 (32.5)	N.A. (14.29, N.A.)	111	28 (25.2)	N.A.	1.095 (0.664, 1.806) 0.7231	
>= 75	34	12 (35.3)	N.A. (7.75, N.A.)	37	13 (35.1)	N.A. (3.52, N.A.)	0.670 (0.294, 1.529) 0.3363	
SEX								0.7134
FEMALE	68	23 (33.8)	N.A. (11.01, N.A.)	65	18 (27.7)	N.A.	0.963 (0.504, 1.842) 0.9089	
MALE	236	71 (30.1)	N.A.	223	49 (22.0)	N.A.	1.134 (0.779, 1.652) 0.5118	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.5982
WHITE	211	75 (35.5)	N.A. (22.80, N.A.)	214	57 (26.6)	N.A.	1.157 (0.812, 1.650) 0.4188	
ASIAN	75	14 (18.7)	N.A.	59	9 (15.3)	N.A.	0.748 (0.300, 1.868) 0.5345	
OTHER	17	5 (29.4)	N.A. (6.21, N.A.)	12	1 (8.3)	N.A.	3.084 (0.352, 27.011) 0.2848	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5399
US	19	6 (31.6)	11.53 (7.49, N.A.)	20	3 (15.0)	N.A.	1.686 (0.401, 7.080) 0.4709	
ASIA	72	14 (19.4)	N.A.	57	9 (15.8)	N.A.	0.747 (0.299, 1.867) 0.5319	
EUROPE	134	44 (32.8)	N.A. (18.40, N.A.)	134	27 (20.1)	N.A.	1.331 (0.810, 2.186) 0.2569	
REST OF THE WORLD	79	30 (38.0)	N.A. (9.79, N.A.)	77	28 (36.4)	N.A.	1.012 (0.600, 1.707) 0.9671	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.9744
0	162	49 (30.2)	N.A.	155	34 (21.9)	N.A.	1.097 (0.694, 1.734) 0.6935	
1	140	45 (32.1)	N.A. (18.40, N.A.)	133	33 (24.8)	N.A.	1.091 (0.688, 1.731) 0.7103	
LIVER METASTASIS								0.5644
YES	62	18 (29.0)	N.A.	59	17 (28.8)	N.A.	0.962 (0.492, 1.880) 0.9104	
NO	242	76 (31.4)	N.A.	229	50 (21.8)	N.A.	1.134 (0.782, 1.645) 0.5062	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2645
STAGE III	37	9 (24.3)	N.A. (17.25, N.A.)	24	7 (29.2)	N.A. (4.04, N.A.)	0.583 (0.201, 1.686) 0.3134	
STAGE IV	265	85 (32.1)	N.A.	262	59 (22.5)	N.A.	1.193 (0.847, 1.681) 0.3131	
PRIOR RADIOTHERAPY								0.2314
YES	26	8 (30.8)	N.A. (7.49, N.A.)	22	9 (40.9)	N.A. (2.99, N.A.)	0.598 (0.226, 1.582) 0.2926	
NO	278	86 (30.9)	N.A.	266	58 (21.8)	N.A.	1.160 (0.821, 1.639) 0.4007	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.1171
YES	88	26 (29.5)	N.A. (18.40, N.A.)	61	8 (13.1)	N.A.	1.843 (0.814, 4.171) 0.1366	
NO	216	68 (31.5)	N.A.	227	59 (26.0)	N.A.	1.001 (0.698, 1.435) 0.9977	
PD-L1 STATUS (IRT)								0.5758
>=1%	111	34 (30.6)	N.A. (18.40, N.A.)	101	25 (24.8)	N.A.	0.966 (0.563, 1.655) 0.8983	
<1%/INDETERMINATE	193	60 (31.1)	N.A. (22.80, N.A.)	187	42 (22.5)	N.A.	1.170 (0.779, 1.758) 0.4482	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 14.4
Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects - Arm C and D

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.8753
YES	64	20 (31.3)	N.A.	61	17 (27.9)	N.A.	1.106 (0.575, 2.126) 0.7616	
NO	240	74 (30.8)	N.A.	227	50 (22.0)	N.A.	1.088 (0.748, 1.582) 0.6586	

June 2023 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
(1) KME of median time to event. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox proportional hazard (PH) model. HR is nivolumab + SOC over SOC. (3) Unstratified Log-rank test.
(4) Unstratified Cox PH model with treatment, subgroup and treatment*subgroup interaction.
(5) A p-value of <0.05 needs to be indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-subae-ebr2114.sas 29FEB2024:13:57:15

Anhang 4-G-1.4.2: Subgruppenanalysen – Weitere Endpunkte zur Verträglichkeit

Anhang 4-G-1.4.2.1: Subgruppenanalysen für imUE

Anhang 4-G-1.4.2.1.1: Subgruppenanalysen für jegliche imUE

Protocol: CA209901

Table 17.1
Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	89 (29.3)	N.A.	288	2 (0.7)	N.A.	35.545 (8.725,>99.999) <0.0001	
PD-L1 STATUS								0.9835
>= 1%	112	39 (34.8)	N.A. (11.47, N.A.)	100	0	N.E.	N.E. <0.0001	
< 1%	192	50 (26.0)	N.A.	188	2 (1.1)	N.A.	21.024 (5.090, 86.835) <0.0001	
AGE CATEGORIZATION								0.9886
< 65	150	43 (28.7)	N.A.	140	1 (0.7)	N.A.	31.197 (4.269,>99.999) <0.0001	
>= 65 AND < 75	120	33 (27.5)	N.A. (14.42, N.A.)	111	1 (0.9)	N.A.	26.914 (3.659,>99.999) <0.0001	
>= 75	34	13 (38.2)	N.A. (6.11, N.A.)	37	0	N.E.	N.E. 0.0003	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:18

Protocol: CA209901

Table 17.1
Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9802
FEMALE	68	18 (26.5)	N.A.	65	0	N.E.	N.E. 0.0002	
MALE	236	71 (30.1)	N.A. (14.42, N.A.)	223	2 (0.9)	N.A.	28.488 (6.959,>99.999) <0.0001	
RACE								0.7437
WHITE	211	60 (28.4)	N.A.	214	1 (0.5)	N.A.	48.590 (6.714,>99.999) <0.0001	
ASIAN	75	24 (32.0)	N.A. (11.47, N.A.)	59	1 (1.7)	N.A.	17.183 (2.308,>99.999) 0.0001	
OTHER	17	5 (29.4)	N.A. (4.44, N.A.)	12	0	N.E.	N.E. 0.0505	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:18

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Table 17.1
Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9996
US	19	5 (26.3)	N.A. (5.09, N.A.)	20	0	N.E.	N.E. 0.0128	
ASIA	72	23 (31.9)	N.A. (11.47, N.A.)	57	1 (1.8)	N.A.	16.145 (2.163,>99.999) 0.0002	
EUROPE	134	37 (27.6)	N.A.	134	0	N.E.	N.E. <0.0001	
REST OF THE WORLD	79	24 (30.4)	N.A. (13.60, N.A.)	77	1 (1.3)	N.A.	20.661 (2.778,>99.999) <0.0001	
BASELINE ECOG PERFORMANCE STATUS								0.7987
0	162	53 (32.7)	N.A. (13.77, N.A.)	155	1 (0.6)	N.A.	40.663 (5.595,>99.999) <0.0001	
1	140	36 (25.7)	N.A.	133	1 (0.8)	N.A.	30.729 (4.200,>99.999) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:18

Protocol: CA209901

Table 17.1
Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS								0.4828
YES	62	20 (32.3)	N.A. (6.18, N.A.)	59	1 (1.7)	N.A.	20.366 (2.728,>99.999) <0.0001	
NO	242	69 (28.5)	N.A.	229	1 (0.4)	N.A.	50.660 (7.006,>99.999) <0.0001	
DISEASE STAGE AT STUDY ENTRY								0.9816
STAGE III	37	14 (37.8)	14.42 (7.85, N.A.)	24	0	N.E.	N.E. 0.0129	
STAGE IV	265	74 (27.9)	N.A.	262	2 (0.8)	N.A.	32.197 (7.879,>99.999) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:18

Protocol: CA209901

Table 17.1
Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9838
YES	26	5 (19.2)	N.A.	22	0	N.E.	N.E.	
							0.0383	
NO	278	84 (30.2)	N.A.	266	2 (0.8)	N.A.	33.518	
							(8.216,>99.999)	
							<0.0001	
PRIOR SYSTEMIC CANCER THERAPY								0.9805
YES	88	24 (27.3)	N.A.	61	0	N.E.	N.E.	
			(13.77, N.A.)				0.0001	
NO	216	65 (30.1)	N.A.	227	2 (0.9)	N.A.	28.587	
							(6.969,>99.999)	
							<0.0001	
PD-L1 STATUS (IRT)								0.9835
>=1%	111	39 (35.1)	N.A.	101	0	N.E.	N.E.	
			(11.47, N.A.)				<0.0001	
<1%/INDETERMINATE	193	50 (25.9)	N.A.	187	2 (1.1)	N.A.	20.756	
							(5.025, 85.727)	
							<0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:18

Protocol: CA209901

Table 17.1
Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.4596
YES	64	20 (31.3)	N.A. (6.18, N.A.)	61	1 (1.6)	N.A.	20.048 (2.685,>99.999) <0.0001	
NO	240	69 (28.8)	N.A.	227	1 (0.4)	N.A.	50.867 (7.035,>99.999) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:18

Anhang 4-G-1.4.2.1.2: Subgruppenanalysen für schwere imUE

Protocol: CA209901

Table 17.2
Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	20 (6.6)	N.A.	288	0	N.E.	N.E. 0.0062	
PD-L1 STATUS								0.9997
>= 1%	112	11 (9.8)	N.A.	100	0	N.E.	N.E. 0.0552	
< 1%	192	9 (4.7)	N.A.	188	0	N.E.	N.E. 0.0534	
AGE CATEGORIZATION								>0.9999
< 65	150	6 (4.0)	N.A.	140	0	N.E.	N.E. 0.1074	
>= 65 AND < 75	120	10 (8.3)	N.A.	111	0	N.E.	N.E. 0.1583	
>= 75	34	4 (11.8)	N.A.	37	0	N.E.	N.E. 0.0806	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:21

Protocol: CA209901

Table 17.2
Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9998
FEMALE	68	7 (10.3)	N.A.	65	0	N.E.	N.E.	
							0.0936	
MALE	236	13 (5.5)	N.A.	223	0	N.E.	N.E.	
							0.0311	
RACE								>0.9999
WHITE	211	13 (6.2)	N.A.	214	0	N.E.	N.E.	
							0.0230	
ASIAN	75	6 (8.0)	N.A.	59	0	N.E.	N.E.	
							0.1368	
OTHER	17	1 (5.9)	N.A.	12	0	N.E.	N.E.	
			(25.00, N.A.)				N.A.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:21

Protocol: CA209901

Table 17.2
Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
US	19	0	N.M.E.	20	0	N.M.E.	N.M.E.	
ASIA	72	6 (8.3)	N.M.E.	57	0	N.M.E.	N.M.E.	
EUROPE	134	9 (6.7)	N.M.E.	134	0	N.M.E.	N.M.E.	
REST OF THE WORLD	79	5 (6.3)	N.M.E.	77	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS								0.9997
0	162	15 (9.3)	N.A.	155	0	N.E.	N.E. 0.0295	
1	140	5 (3.6)	N.A.	133	0	N.E.	N.E. 0.0991	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:21

Protocol: CA209901

Table 17.2
Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS								>0.9999
YES	62	3 (4.8)	N.A.	59	0	N.E.	N.E. 0.1670	
NO	242	17 (7.0)	N.A.	229	0	N.E.	N.E. 0.0183	
DISEASE STAGE AT STUDY ENTRY								0.9998
STAGE III	37	1 (2.7)	N.A.	24	0	N.E.	N.E. 0.6831	
STAGE IV	265	19 (7.2)	N.A.	262	0	N.E.	N.E. 0.0056	
PRIOR RADIOTHERAPY								0.9998
YES	26	3 (11.5)	N.A.	22	0	N.E.	N.E. 0.1133	
NO	278	17 (6.1)	N.A.	266	0	N.E.	N.E. 0.0284	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:21

Protocol: CA209901

Table 17.2
Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								>0.9999
YES	88	5 (5.7)	N.A.	61	0	N.E.	N.E. 0.2348	
NO	216	15 (6.9)	N.A.	227	0	N.E.	N.E. 0.0130	
PD-L1 STATUS (IRT)								0.9997
>=1%	111	11 (9.9)	N.A.	101	0	N.E.	N.E. 0.0529	
<1%/INDETERMINATE	193	9 (4.7)	N.A.	187	0	N.E.	N.E. 0.0548	
LIVER METASTASIS (IRT)								>0.9999
YES	64	3 (4.7)	N.A.	61	0	N.E.	N.E. 0.1676	
NO	240	17 (7.1)	N.A.	227	0	N.E.	N.E. 0.0181	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:21

Anhang 4-G-1.4.2.1.3: Subgruppenanalysen für schwerwiegende imUE

Protocol: CA209901

Table 17.3
Serious Immune-mediated Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	18 (5.9)	N.A.	288	0	N.E.	N.E. 0.0062	
PD-L1 STATUS								N.M.E.
>= 1%	112	9 (8.0)	N.M.E.	100	0	N.M.E.	N.M.E.	
< 1%	192	9 (4.7)	N.M.E.	188	0	N.M.E.	N.M.E.	
AGE CATEGORIZATION								N.M.E.
< 65	150	8 (5.3)	N.M.E.	140	0	N.M.E.	N.M.E.	
>= 65 AND < 75	120	7 (5.8)	N.M.E.	111	0	N.M.E.	N.M.E.	
>= 75	34	3 (8.8)	N.M.E.	37	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:26

Protocol: CA209901

Table 17.3
Serious Immune-mediated Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9997
FEMALE	68	8 (11.8)	N.A.	65	0	N.E.	N.E.	
							0.0477	
MALE	236	10 (4.2)	N.A.	223	0	N.E.	N.E.	
							0.0553	
RACE								>0.9999
WHITE	211	10 (4.7)	N.A.	214	0	N.E.	N.E.	
							0.0397	
ASIAN	75	7 (9.3)	N.A.	59	0	N.E.	N.E.	
							0.0872	
OTHER	17	1 (5.9)	N.A.	12	0	N.E.	N.E.	
			(25.00, N.A.)				N.A.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:26

Protocol: CA209901

Table 17.3
Serious Immune-mediated Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
US	19	0	N.E.	20	0	N.E.	N.E. N.E.	
ASIA	72	7 (9.7)	N.A.	57	0	N.E.	N.E. 0.0878	
EUROPE	134	10 (7.5)	N.A.	134	0	N.E.	N.E. 0.0768	
REST OF THE WORLD	79	1 (1.3)	N.A.	77	0	N.E.	N.E. 0.3299	
BASELINE ECOG PERFORMANCE STATUS								0.9998
0	162	13 (8.0)	N.A.	155	0	N.E.	N.E. 0.0299	
1	140	5 (3.6)	N.A.	133	0	N.E.	N.E. 0.0906	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:26

Protocol: CA209901

Table 17.3
Serious Immune-mediated Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS								>0.9999
YES	62	3 (4.8)	N.A.	59	0	N.E.	N.E. 0.0977	
NO	242	15 (6.2)	N.A.	229	0	N.E.	N.E. 0.0307	
DISEASE STAGE AT STUDY ENTRY								0.9998
STAGE III	37	1 (2.7)	N.A.	24	0	N.E.	N.E. 0.6831	
STAGE IV	265	17 (6.4)	N.A.	262	0	N.E.	N.E. 0.0056	
PRIOR RADIOTHERAPY								0.9999
YES	26	2 (7.7)	N.A.	22	0	N.E.	N.E. 0.1889	
NO	278	16 (5.8)	N.A.	266	0	N.E.	N.E. 0.0170	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:26

Protocol: CA209901

Table 17.3
Serious Immune-mediated Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any imAEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any ImAEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								>0.9999
YES	88	4 (4.5)	N.A.	61	0	N.E.	N.E. 0.3961	
NO	216	14 (6.5)	N.A.	227	0	N.E.	N.E. 0.0075	
PD-L1 STATUS (IRT)								N.M.E.
>=1%	111	9 (8.1)	N.M.E.	101	0	N.M.E.	N.M.E.	
<1%/INDETERMINATE	193	9 (4.7)	N.M.E.	187	0	N.M.E.	N.M.E.	
LIVER METASTASIS (IRT)								>0.9999
YES	64	3 (4.7)	N.A.	61	0	N.E.	N.E. 0.0985	
NO	240	15 (6.3)	N.A.	227	0	N.E.	N.E. 0.0304	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:24:26

Anhang 4-G-1.4.2.2: Subgruppenanalysen für spezifische UE

Anhang 4-G-1.4.2.2.1: Subgruppenanalysen für jegliche spezifische UE

Protocol: CA209901

Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	227 (74.7)	2.53 (2.07, 3.68)	288	141 (49.0)	5.78 (2.92, N.A.)	1.542 (1.247, 1.907) <0.0001	
PD-L1 STATUS								0.6528
>= 1%	112	85 (75.9)	2.53 (1.35, 4.27)	100	47 (47.0)	N.A. (2.30, N.A.)	1.646 (1.148, 2.360) 0.0060	
< 1%	192	142 (74.0)	2.66 (1.94, 3.78)	188	94 (50.0)	5.09 (2.30, N.A.)	1.488 (1.143, 1.937) 0.0028	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
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Protocol: CA209901

Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.0071*
< 65	150	116 (77.3)	2.30 (1.05, 4.14)	140	73 (52.1)	3.52 (2.04, N.A.)	1.421 (1.054, 1.914) 0.0197	
>= 65 AND < 75	120	84 (70.0)	3.32 (2.10, 4.70)	111	60 (54.1)	3.29 (2.10, N.A.)	1.264 (0.906, 1.765) 0.1646	
>= 75	34	27 (79.4)	1.69 (0.69, 4.27)	37	8 (21.6)	N.A.	4.972 (2.247, 11.002) <0.0001	
SEX								0.6520
FEMALE	68	48 (70.6)	3.32 (1.51, 5.32)	65	33 (50.8)	3.48 (2.10, N.A.)	1.445 (0.925, 2.256) 0.1016	
MALE	236	179 (75.8)	2.50 (1.61, 3.68)	223	108 (48.4)	5.91 (2.92, N.A.)	1.563 (1.227, 1.991) 0.0002	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:36

Protocol: CA209901

Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.8716
WHITE	211	159 (75.4)	2.66 (2.07, 3.78)	214	105 (49.1)	5.78 (2.79, N.A.)	1.479 (1.152, 1.898) 0.0019	
ASIAN	75	53 (70.7)	3.38 (0.85, 5.19)	59	27 (45.8)	N.A. (2.30, N.A.)	1.635 (1.025, 2.610) 0.0350	
OTHER	17	14 (82.4)	1.74 (0.16, 2.53)	12	7 (58.3)	1.71 (0.26, N.A.)	1.753 (0.704, 4.364) 0.2219	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Protocol: CA209901

Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.2930
US	19	14 (73.7)	1.64 (0.33, 5.98)	20	14 (70.0)	0.79 (0.23, N.A.)	0.906 (0.431, 1.907) 0.8056	
ASIA	72	50 (69.4)	3.98 (0.85, 5.52)	57	25 (43.9)	N.A. (2.30, N.A.)	1.675 (1.032, 2.719) 0.0330	
EUROPE	134	100 (74.6)	3.06 (2.10, 4.99)	134	58 (43.3)	N.A. (3.25, N.A.)	1.666 (1.198, 2.315) 0.0021	
REST OF THE WORLD	79	63 (79.7)	2.07 (1.35, 3.32)	77	44 (57.1)	3.15 (1.51, N.A.)	1.467 (0.996, 2.161) 0.0498	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:36

Protocol: CA209901

Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.2817
0	162	121 (74.7)	3.19 (2.07, 5.09)	155	80 (51.6)	4.67 (2.43, N.A.)	1.373 (1.030, 1.832) 0.0290	
1	140	104 (74.3)	2.30 (1.58, 3.42)	133	61 (45.9)	N.A. (2.23, N.A.)	1.746 (1.271, 2.399) 0.0005	
LIVER METASTASIS								0.9859
YES	62	48 (77.4)	1.58 (0.85, 3.48)	59	33 (55.9)	2.92 (1.45, N.A.)	1.566 (1.003, 2.446) 0.0457	
NO	242	179 (74.0)	3.06 (2.10, 3.98)	229	108 (47.2)	N.A. (3.15, N.A.)	1.543 (1.212, 1.966) 0.0004	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Protocol: CA209901

Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9370
STAGE III	37	28 (75.7)	2.37 (0.89, 6.14)	24	12 (50.0)	4.67 (1.18, N.A.)	1.461 (0.736, 2.903) 0.2761	
STAGE IV	265	197 (74.3)	2.83 (1.94, 3.68)	262	127 (48.5)	5.91 (2.92, N.A.)	1.562 (1.247, 1.956) <0.0001	
PRIOR RADIOTHERAPY								0.8166
YES	26	19 (73.1)	2.07 (0.72, 5.32)	22	12 (54.5)	2.45 (0.79, N.A.)	1.448 (0.702, 2.985) 0.3128	
NO	278	208 (74.8)	2.53 (1.94, 3.84)	266	129 (48.5)	5.78 (3.02, N.A.)	1.550 (1.241, 1.936) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Protocol: CA209901

Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.5918
YES	88	61 (69.3)	3.35 (1.38, 5.16)	61	29 (47.5)	N.A. (1.64, N.A.)	1.357 (0.865, 2.129) 0.1747	
NO	216	166 (76.9)	2.53 (1.64, 3.42)	227	112 (49.3)	5.09 (2.79, N.A.)	1.616 (1.269, 2.058) <0.0001	
PD-L1 STATUS (IRT)								0.7539
>=1%	111	84 (75.7)	3.06 (1.35, 4.70)	101	48 (47.5)	4.67 (2.23, N.A.)	1.611 (1.126, 2.306) 0.0083	
<1%/INDETERMINATE	193	143 (74.1)	2.53 (1.94, 3.78)	187	93 (49.7)	5.78 (2.79, N.A.)	1.504 (1.155, 1.959) 0.0022	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 15.1
Select Adverse Events: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.9871
YES	64	50 (78.1)	1.58 (0.76, 3.35)	61	34 (55.7)	2.92 (1.18, N.A.)	1.582 (1.021, 2.451) 0.0373	
NO	240	177 (73.8)	3.09 (2.10, 4.14)	227	107 (47.1)	N.A. (3.15, N.A.)	1.538 (1.206, 1.961) 0.0004	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Anhang 4-G-1.4.2.2.2: Subgruppenanalysen für schwere spezifische UE

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	56 (18.4)	N.A.	288	16 (5.6)	N.A.	2.551 (1.439, 4.524) 0.0009	
PD-L1 STATUS								0.4266
>= 1%	112	23 (20.5)	N.A.	100	8 (8.0)	N.A.	1.983 (0.861, 4.568) 0.1012	
< 1%	192	33 (17.2)	N.A.	188	8 (4.3)	N.A.	3.103 (1.404, 6.855) 0.0032	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:39

Protocol: CA209901

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.8738
< 65	150	29 (19.3)	N.A.	140	7 (5.0)	N.A.	3.275 (1.416, 7.572) 0.0033	
>= 65 AND < 75	120	21 (17.5)	N.A.	111	7 (6.3)	N.A.	1.769 (0.709, 4.411) 0.2156	
>= 75	34	6 (17.6)	N.A.	37	2 (5.4)	N.A.	2.770 (0.540, 14.211) 0.2040	
SEX								0.4876
FEMALE	68	15 (22.1)	N.A.	65	3 (4.6)	N.A.	4.025 (1.138, 14.238) 0.0195	
MALE	236	41 (17.4)	N.A.	223	13 (5.8)	N.A.	2.227 (1.167, 4.250) 0.0127	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:39

Protocol: CA209901

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.8880
WHITE	211	39 (18.5)	N.A.	214	11 (5.1)	N.A.	2.915 (1.470, 5.778) 0.0013	
ASIAN	75	14 (18.7)	N.A.	59	4 (6.8)	N.A.	2.036 (0.642, 6.463) 0.2181	
OTHER	17	3 (17.6)	N.A. (9.07, N.A.)	12	1 (8.3)	N.A.	0.751 (0.047, 12.030) 0.8394	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:39

Protocol: CA209901

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.4049
US	19	4 (21.1)	N.A. (5.98, N.A.)	20	2 (10.0)	N.A.	2.244 (0.411, 12.255) 0.3377	
ASIA	72	14 (19.4)	N.A.	57	4 (7.0)	N.A.	2.027 (0.637, 6.450) 0.2219	
EUROPE	134	23 (17.2)	N.A.	134	3 (2.2)	N.A.	5.034 (1.466, 17.287) 0.0044	
REST OF THE WORLD	79	15 (19.0)	N.A.	77	7 (9.1)	N.A.	1.781 (0.711, 4.466) 0.2118	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:39

Protocol: CA209901

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.1381
0	162	33 (20.4)	N.A.	155	6 (3.9)	N.A.	3.442 (1.396, 8.487) 0.0044	
1	140	22 (15.7)	N.A.	133	10 (7.5)	N.A.	1.902 (0.892, 4.055) 0.0904	
LIVER METASTASIS								0.0422*
YES	62	20 (32.3)	N.A. (12.98, N.A.)	59	2 (3.4)	N.A.	9.842 (2.286, 42.378) 0.0002	
NO	242	36 (14.9)	N.A.	229	14 (6.1)	N.A.	1.623 (0.845, 3.117) 0.1420	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:39

Protocol: CA209901

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.0017*
STAGE III	37	4 (10.8)	N.A.	24	5 (20.8)	N.A.	0.420 (0.110, 1.602) 0.1910	
STAGE IV	265	52 (19.6)	N.A.	262	11 (4.2)	N.A.	3.601 (1.848, 7.017) <0.0001	
PRIOR RADIOTHERAPY								0.6016
YES	26	9 (34.6)	N.A. (5.06, N.A.)	22	2 (9.1)	N.A.	4.205 (0.907, 19.485) 0.0458	
NO	278	47 (16.9)	N.A.	266	14 (5.3)	N.A.	2.306 (1.240, 4.289) 0.0067	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:39

Protocol: CA209901

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.8552
YES	88	13 (14.8)	N.A.	61	3 (4.9)	N.A.	2.425 (0.669, 8.797) 0.1640	
NO	216	43 (19.9)	N.A.	227	13 (5.7)	N.A.	2.635 (1.389, 5.000) 0.0021	
PD-L1 STATUS (IRT)								0.4675
>=1%	111	23 (20.7)	N.A.	101	8 (7.9)	N.A.	2.027 (0.880, 4.668) 0.0904	
<1%/INDETERMINATE	193	33 (17.1)	N.A.	187	8 (4.3)	N.A.	3.066 (1.388, 6.775) 0.0036	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Protocol: CA209901

Table 15.2
Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.0249*
YES	64	22 (34.4)	N.A. (8.97, N.A.)	61	2 (3.3)	N.A.	11.146 (2.607, 47.662) <0.0001	
NO	240	34 (14.2)	N.A.	227	14 (6.2)	N.A.	1.482 (0.764, 2.873) 0.2416	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Anhang 4-G-1.4.2.2.3: Subgruppenanalysen für schwerwiegende spezifische UE

Protocol: CA209901

Table 15.3
Serious Select Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	36 (11.8)	N.A.	288	13 (4.5)	N.A.	1.793 (0.920, 3.495) 0.0821	
PD-L1 STATUS								0.3421
>= 1%	112	15 (13.4)	N.A.	100	7 (7.0)	N.A.	1.292 (0.500, 3.339) 0.5951	
< 1%	192	21 (10.9)	N.A.	188	6 (3.2)	N.A.	2.353 (0.911, 6.081) 0.0691	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Protocol: CA209901

Table 15.3
Serious Select Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.9649
< 65	150	18 (12.0)	N.A.	140	6 (4.3)	N.A.	1.935 (0.736, 5.084) 0.1732	
>= 65 AND < 75	120	14 (11.7)	N.A.	111	5 (4.5)	N.A.	1.670 (0.562, 4.960) 0.3511	
>= 75	34	4 (11.8)	N.A.	37	2 (5.4)	N.A.	1.678 (0.285, 9.895) 0.5634	
SEX								0.9606
FEMALE	68	11 (16.2)	N.A.	65	4 (6.2)	N.A.	2.012 (0.608, 6.657) 0.2428	
MALE	236	25 (10.6)	N.A.	223	9 (4.0)	N.A.	1.714 (0.766, 3.834) 0.1845	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Protocol: CA209901

Table 15.3
Serious Select Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.7774
WHITE	211	25 (11.8)	N.A.	214	10 (4.7)	N.A.	1.977 (0.926, 4.219) 0.0726	
ASIAN	75	9 (12.0)	N.A.	59	2 (3.4)	N.A.	1.967 (0.385, 10.048) 0.4079	
OTHER	17	2 (11.8)	N.A. (9.07, N.A.)	12	1 (8.3)	N.A.	<0.001 (<0.001, N.A.) 0.2482	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:42

Protocol: CA209901

Table 15.3
Serious Select Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.6206
US	19	0	N.E.	20	2 (10.0)	N.A.	N.E. 0.1741	
ASIA	72	9 (12.5)	N.A.	57	2 (3.5)	N.A.	1.940 (0.377, 9.977) 0.4193	
EUROPE	134	21 (15.7)	N.A.	134	5 (3.7)	N.A.	2.637 (0.949, 7.322) 0.0537	
REST OF THE WORLD	79	6 (7.6)	N.A.	77	4 (5.2)	N.A.	1.474 (0.416, 5.225) 0.5450	
BASELINE ECOG PERFORMANCE STATUS								0.7405
0	162	22 (13.6)	N.A.	155	7 (4.5)	N.A.	1.697 (0.678, 4.244) 0.2533	
1	140	14 (10.0)	N.A.	133	6 (4.5)	N.A.	1.918 (0.722, 5.099) 0.1839	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:42

Protocol: CA209901

Table 15.3
Serious Select Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS								0.2533
YES	62	10 (16.1)	N.A.	59	2 (3.4)	N.A.	4.570 (0.990, 21.101) 0.0327	
NO	242	26 (10.7)	N.A.	229	11 (4.8)	N.A.	1.317 (0.613, 2.830) 0.4788	
DISEASE STAGE AT STUDY ENTRY								0.0122*
STAGE III	37	3 (8.1)	N.A.	24	4 (16.7)	N.A.	0.387 (0.083, 1.792) 0.2088	
STAGE IV	265	33 (12.5)	N.A.	262	9 (3.4)	N.A.	2.464 (1.140, 5.324) 0.0179	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:42

Protocol: CA209901

Table 15.3
Serious Select Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9217
YES	26	5 (19.2)	N.A.	22	2 (9.1)	N.A.	2.371 (0.460, 12.229) 0.2877	
NO	278	31 (11.2)	N.A.	266	11 (4.1)	N.A.	1.690 (0.813, 3.513) 0.1554	
PRIOR SYSTEMIC CANCER THERAPY								0.8947
YES	88	7 (8.0)	N.A.	61	2 (3.3)	N.A.	1.457 (0.269, 7.879) 0.6602	
NO	216	29 (13.4)	N.A.	227	11 (4.8)	N.A.	1.944 (0.940, 4.023) 0.0683	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:42

Protocol: CA209901

Table 15.3
Serious Select Adverse Events : Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any Select AEs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any Select AEs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 STATUS (IRT)								0.3737
>=1%	111	15 (13.5)	N.A.	101	7 (6.9)	N.A.	1.321 (0.511, 3.412) 0.5642	
<1%/INDETERMINATE	193	21 (10.9)	N.A.	187	6 (3.2)	N.A.	2.327 (0.900, 6.013) 0.0730	
LIVER METASTASIS (IRT)								0.1385
YES	64	12 (18.8)	N.A.	61	2 (3.3)	N.A.	5.698 (1.265, 25.667) 0.0105	
NO	240	24 (10.0)	N.A.	227	11 (4.8)	N.A.	1.144 (0.522, 2.507) 0.7375	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:23:42

Anhang 4-G-1.4.2.3: Subgruppenanalysen für OESI

Anhang 4-G-1.4.2.3.1: Subgruppenanalysen für jegliche OESI

Protocol: CA209901

Table 19.1
Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	9 (3.0)	N.A.	288	1 (0.3)	N.A.	4.597 (0.538, 39.250) 0.1257	
PD-L1 STATUS								N.M.E.
>= 1%	112	2 (1.8)	N.M.E.	100	0	N.M.E.	N.M.E.	
< 1%	192	7 (3.6)	N.M.E.	188	1 (0.5)	N.M.E.	N.M.E.	
AGE CATEGORIZATION								N.M.E.
< 65	150	6 (4.0)	N.M.E.	140	0	N.M.E.	N.M.E.	
>= 65 AND < 75	120	2 (1.7)	N.M.E.	111	1 (0.9)	N.M.E.	N.M.E.	
>= 75	34	1 (2.9)	N.M.E.	37	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:25

Protocol: CA209901

Table 19.1
Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
FEMALE	68	1 (1.5)	N.M.E.	65	0	N.M.E.	N.M.E.	
MALE	236	8 (3.4)	N.M.E.	223	1 (0.4)	N.M.E.	N.M.E.	
RACE								N.M.E.
WHITE	211	7 (3.3)	N.M.E.	214	0	N.M.E.	N.M.E.	
ASIAN	75	2 (2.7)	N.M.E.	59	1 (1.7)	N.M.E.	N.M.E.	
OTHER	17	0	N.M.E.	12	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:25

Protocol: CA209901

Table 19.1
Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
US	19	2 (10.5)	N.M.E.	20	0	N.M.E.	N.M.E.	
ASIA	72	2 (2.8)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	
EUROPE	134	3 (2.2)	N.M.E.	134	0	N.M.E.	N.M.E.	
REST OF THE WORLD	79	2 (2.5)	N.M.E.	77	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS								N.M.E.
0	162	3 (1.9)	N.M.E.	155	1 (0.6)	N.M.E.	N.M.E.	
1	140	6 (4.3)	N.M.E.	133	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:25

Table 19.1
Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS								N.M.E.
YES	62	2 (3.2)	N.M.E.	59	0	N.M.E.	N.M.E.	
NO	242	7 (2.9)	N.M.E.	229	1 (0.4)	N.M.E.	N.M.E.	
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE III	37	3 (8.1)	N.M.E.	24	0	N.M.E.	N.M.E.	
STAGE IV	265	6 (2.3)	N.M.E.	262	1 (0.4)	N.M.E.	N.M.E.	
PRIOR RADIOTHERAPY								N.M.E.
YES	26	1 (3.8)	N.M.E.	22	0	N.M.E.	N.M.E.	
NO	278	8 (2.9)	N.M.E.	266	1 (0.4)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:25

Protocol: CA209901

Table 19.1
Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	88	2 (2.3)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	216	7 (3.2)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	
PD-L1 STATUS (IRT)								N.M.E.
>=1%	111	2 (1.8)	N.M.E.	101	0	N.M.E.	N.M.E.	
<1%/INDETERMINATE	193	7 (3.6)	N.M.E.	187	1 (0.5)	N.M.E.	N.M.E.	
LIVER METASTASIS (IRT)								N.M.E.
YES	64	2 (3.1)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	240	7 (2.9)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:25

Anhang 4-G-1.4.2.3.2: Subgruppenanalysen für schwere OESI

Table 19.2
Other Events of Special Interest with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	8 (2.6)	N.A.	288	1 (0.3)	N.A.	3.658 (0.410, 32.604) 0.2138	
PD-L1 STATUS								N.M.E.
>= 1%	112	1 (0.9)	N.M.E.	100	0	N.M.E.	N.M.E.	
< 1%	192	7 (3.6)	N.M.E.	188	1 (0.5)	N.M.E.	N.M.E.	
AGE CATEGORIZATION								N.M.E.
< 65	150	5 (3.3)	N.M.E.	140	0	N.M.E.	N.M.E.	
>= 65 AND < 75	120	2 (1.7)	N.M.E.	111	1 (0.9)	N.M.E.	N.M.E.	
>= 75	34	1 (2.9)	N.M.E.	37	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:28

Protocol: CA209901

Table 19.2
Other Events of Special Interest with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
FEMALE	68	1 (1.5)	N.M.E.	65	0	N.M.E.	N.M.E.	
MALE	236	7 (3.0)	N.M.E.	223	1 (0.4)	N.M.E.	N.M.E.	
RACE								N.M.E.
WHITE	211	7 (3.3)	N.M.E.	214	0	N.M.E.	N.M.E.	
ASIAN	75	1 (1.3)	N.M.E.	59	1 (1.7)	N.M.E.	N.M.E.	
OTHER	17	0	N.M.E.	12	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:28

Protocol: CA209901

Table 19.2
Other Events of Special Interest with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
US	19	2 (10.5)	N.M.E.	20	0	N.M.E.	N.M.E.	
ASIA	72	1 (1.4)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	
EUROPE	134	3 (2.2)	N.M.E.	134	0	N.M.E.	N.M.E.	
REST OF THE WORLD	79	2 (2.5)	N.M.E.	77	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS								N.M.E.
0	162	2 (1.2)	N.M.E.	155	1 (0.6)	N.M.E.	N.M.E.	
1	140	6 (4.3)	N.M.E.	133	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 19.2
Other Events of Special Interest with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS								N.M.E.
YES	62	2 (3.2)	N.M.E.	59	0	N.M.E.	N.M.E.	
NO	242	6 (2.5)	N.M.E.	229	1 (0.4)	N.M.E.	N.M.E.	
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE III	37	3 (8.1)	N.M.E.	24	0	N.M.E.	N.M.E.	
STAGE IV	265	5 (1.9)	N.M.E.	262	1 (0.4)	N.M.E.	N.M.E.	
PRIOR RADIOTHERAPY								N.M.E.
YES	26	1 (3.8)	N.M.E.	22	0	N.M.E.	N.M.E.	
NO	278	7 (2.5)	N.M.E.	266	1 (0.4)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 19.2
Other Events of Special Interest with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	88	2 (2.3)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	216	6 (2.8)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	
PD-L1 STATUS (IRT)								N.M.E.
>=1%	111	1 (0.9)	N.M.E.	101	0	N.M.E.	N.M.E.	
<1%/INDETERMINATE	193	7 (3.6)	N.M.E.	187	1 (0.5)	N.M.E.	N.M.E.	
LIVER METASTASIS (IRT)								N.M.E.
YES	64	2 (3.1)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	240	6 (2.5)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:28

Anhang 4-G-1.4.2.3.3: Subgruppenanalysen für schwerwiegende OESI

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Table 19.3
Serious Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	8 (2.6)	N.A.	288	1 (0.3)	N.A.	4.589 (0.537, 39.186) 0.1262	
PD-L1 STATUS								N.M.E.
>= 1%	112	2 (1.8)	N.M.E.	100	0	N.M.E.	N.M.E.	
< 1%	192	6 (3.1)	N.M.E.	188	1 (0.5)	N.M.E.	N.M.E.	
AGE CATEGORIZATION								N.M.E.
< 65	150	5 (3.3)	N.M.E.	140	0	N.M.E.	N.M.E.	
>= 65 AND < 75	120	2 (1.7)	N.M.E.	111	1 (0.9)	N.M.E.	N.M.E.	
>= 75	34	1 (2.9)	N.M.E.	37	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:31

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Table 19.3
Serious Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
FEMALE	68	1 (1.5)	N.M.E.	65	0	N.M.E.	N.M.E.	
MALE	236	7 (3.0)	N.M.E.	223	1 (0.4)	N.M.E.	N.M.E.	
RACE								N.M.E.
WHITE	211	6 (2.8)	N.M.E.	214	0	N.M.E.	N.M.E.	
ASIAN	75	2 (2.7)	N.M.E.	59	1 (1.7)	N.M.E.	N.M.E.	
OTHER	17	0	N.M.E.	12	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:31

Table 19.3
Serious Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
US	19	2 (10.5)	N.M.E.	20	0	N.M.E.	N.M.E.	
ASIA	72	2 (2.8)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	
EUROPE	134	2 (1.5)	N.M.E.	134	0	N.M.E.	N.M.E.	
REST OF THE WORLD	79	2 (2.5)	N.M.E.	77	0	N.M.E.	N.M.E.	
BASELINE ECOG PERFORMANCE STATUS								N.M.E.
0	162	2 (1.2)	N.M.E.	155	1 (0.6)	N.M.E.	N.M.E.	
1	140	6 (4.3)	N.M.E.	133	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:31

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Table 19.3
Serious Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS								N.M.E.
YES	62	2 (3.2)	N.M.E.	59	0	N.M.E.	N.M.E.	
NO	242	6 (2.5)	N.M.E.	229	1 (0.4)	N.M.E.	N.M.E.	
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE III	37	2 (5.4)	N.M.E.	24	0	N.M.E.	N.M.E.	
STAGE IV	265	6 (2.3)	N.M.E.	262	1 (0.4)	N.M.E.	N.M.E.	
PRIOR RADIOTHERAPY								N.M.E.
YES	26	1 (3.8)	N.M.E.	22	0	N.M.E.	N.M.E.	
NO	278	7 (2.5)	N.M.E.	266	1 (0.4)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:31

Protocol: CA209901

Table 19.3
Serious Other Events of Special Interest: Subgroup Time-Adjusted Analyses
On Hazard Ratio for Any OESIs
All Treated Subjects - Arm C and D

Select Adverse Events Category: Any OESIs

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	88	1 (1.1)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	216	7 (3.2)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	
PD-L1 STATUS (IRT)								N.M.E.
>=1%	111	2 (1.8)	N.M.E.	101	0	N.M.E.	N.M.E.	
<1%/INDETERMINATE	193	6 (3.1)	N.M.E.	187	1 (0.5)	N.M.E.	N.M.E.	
LIVER METASTASIS (IRT)								N.M.E.
YES	64	2 (3.1)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	240	6 (2.5)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubslae-ebr2114.sas 04MAR2024:10:25:31

Anhang 4-G-1.4.2.4: Subgruppenanalysen für häufige UE auf SOC/PT-Ebene

Anhang 4-G-1.4.2.4.1: Subgruppenanalysen für häufige jegliche UE auf SOC/PT-Ebene

Protocol: CA209901

Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	65 (21.4)	N.A.	288	41 (14.2)	N.A.	1.564 (1.058, 2.313) 0.0238	
PD-L1 STATUS								0.2711
>= 1%	112	24 (21.4)	N.A.	100	10 (10.0)	N.A.	2.188 (1.046, 4.577) 0.0326	
< 1%	192	41 (21.4)	N.A.	188	31 (16.5)	N.A.	1.358 (0.852, 2.165) 0.1990	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.7833
< 65	150	28 (18.7)	N.A.	140	19 (13.6)	N.A.	1.391 (0.777, 2.491) 0.2636	
>= 65 AND < 75	120	32 (26.7)	N.A.	111	18 (16.2)	N.A.	1.811 (1.017, 3.227) 0.0411	
>= 75	34	5 (14.7)	N.A.	37	4 (10.8)	N.A.	1.300 (0.349, 4.841) 0.6952	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2645
FEMALE	68	19 (27.9)	N.A.	65	9 (13.8)	N.A.	2.269 (1.026, 5.017) 0.0372	
MALE	236	46 (19.5)	N.A.	223	32 (14.3)	N.A.	1.381 (0.880, 2.169) 0.1589	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9977
WHITE	211	17 (8.1)	N.A.	214	11 (5.1)	N.A.	1.564 (0.733, 3.340) 0.2430	
ASIAN	75	48 (64.0)	1.38 (0.62, 2.40)	59	30 (50.8)	3.48 (1.18, N.A.)	1.506 (0.953, 2.378) 0.0778	
OTHER	17	0	N.E.	12	0	N.E.	N.E. N.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.4111
US	19	7 (36.8)	N.A. (0.69, N.A.)	20	5 (25.0)	N.A. (2.33, N.A.)	1.624 (0.515, 5.124) 0.3984	
ASIA	72	47 (65.3)	1.38 (0.53, 2.33)	57	29 (50.9)	3.48 (1.18, N.A.)	1.563 (0.983, 2.486) 0.0575	
EUROPE	134	6 (4.5)	N.A.	134	1 (0.7)	N.A.	6.011 (0.724, 49.904) 0.0584	
REST OF THE WORLD	79	5 (6.3)	N.A.	77	6 (7.8)	N.A.	0.782 (0.239, 2.563) 0.6835	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.4012
0	162	38 (23.5)	N.A.	155	21 (13.5)	N.A.	1.828 (1.073, 3.115) 0.0244	
1	140	27 (19.3)	N.A.	133	20 (15.0)	N.A.	1.312 (0.736, 2.339) 0.3576	
LIVER METASTASIS								0.6032
YES	62	9 (14.5)	N.A.	59	7 (11.9)	N.A.	1.238 (0.461, 3.325) 0.6766	
NO	242	56 (23.1)	N.A.	229	34 (14.8)	N.A.	1.635 (1.067, 2.503) 0.0225	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9792
STAGE III	37	6 (16.2)	N.A.	24	0	N.E.	N.E. 0.0417	
STAGE IV	265	59 (22.3)	N.A.	262	40 (15.3)	N.A.	1.519 (1.017, 2.270) 0.0398	
PRIOR RADIOTHERAPY								0.2057
YES	26	6 (23.1)	N.A.	22	1 (4.5)	N.A.	5.510 (0.663, 45.798) 0.0735	
NO	278	59 (21.2)	N.A.	266	40 (15.0)	N.A.	1.459 (0.976, 2.179) 0.0640	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.5238
YES	88	22 (25.0)	N.A.	61	13 (21.3)	N.A.	1.274 (0.642, 2.529) 0.4890	
NO	216	43 (19.9)	N.A.	227	28 (12.3)	N.A.	1.655 (1.028, 2.664) 0.0359	
PD-L1 STATUS (IRT)								0.3695
>=1%	111	24 (21.6)	N.A.	101	11 (10.9)	N.A.	2.030 (0.994, 4.145) 0.0468	
<1%/INDETERMINATE	193	41 (21.2)	N.A.	187	30 (16.0)	N.A.	1.389 (0.867, 2.224) 0.1715	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.8615
YES	64	9 (14.1)	N.A.	61	6 (9.8)	N.A.	1.435 (0.511, 4.032) 0.4953	
NO	240	56 (23.3)	N.A.	227	35 (15.4)	N.A.	1.588 (1.041, 2.423) 0.0304	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	34 (11.2)	N.A.	288	15 (5.2)	N.A.	1.915 (1.034, 3.548) 0.0357	
PD-L1 STATUS								0.5441
>= 1%	112	15 (13.4)	N.A.	100	5 (5.0)	N.A.	2.744 (0.997, 7.552) 0.0416	
< 1%	192	19 (9.9)	N.A.	188	10 (5.3)	N.A.	1.489 (0.676, 3.280) 0.3207	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.3362
< 65	150	19 (12.7)	N.A.	140	12 (8.6)	N.A.	1.219 (0.579, 2.568) 0.6005	
>= 65 AND < 75	120	13 (10.8)	N.A.	111	3 (2.7)	N.A.	3.975 (1.128, 14.006) 0.0205	
>= 75	34	2 (5.9)	N.A.	37	0	N.E.	N.E. 0.1619	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3887
FEMALE	68	8 (11.8)	N.A.	65	2 (3.1)	N.A.	3.803 (0.807, 17.918) 0.0696	
MALE	236	26 (11.0)	N.A.	223	13 (5.8)	N.A.	1.622 (0.822, 3.203) 0.1595	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9998
WHITE	211	28 (13.3)	N.A.	214	12 (5.6)	N.A.	2.069 (1.040, 4.117) 0.0345	
ASIAN	75	6 (8.0)	N.A.	59	2 (3.4)	N.A.	2.369 (0.478, 11.739) 0.2761	
OTHER	17	0	N.E.	12	1 (8.3)	N.A.	N.E. 0.2340	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8024
US	19	0	N.E.	20	4 (20.0)	N.A.	N.E. 0.0457	
ASIA	72	6 (8.3)	N.A.	57	1 (1.8)	N.A.	4.784 (0.576, 39.731) 0.1092	
EUROPE	134	13 (9.7)	N.A.	134	3 (2.2)	N.A.	3.293 (0.915, 11.844) 0.0536	
REST OF THE WORLD	79	15 (19.0)	N.A.	77	7 (9.1)	N.A.	1.992 (0.805, 4.930) 0.1299	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.6916
0	162	12 (7.4)	N.A.	155	6 (3.9)	N.A.	1.597 (0.582, 4.378) 0.3588	
1	140	22 (15.7)	N.A.	133	9 (6.8)	N.A.	2.154 (0.986, 4.706) 0.0493	
LIVER METASTASIS								0.7214
YES	62	9 (14.5)	N.A.	59	5 (8.5)	N.A.	1.753 (0.587, 5.233) 0.3075	
NO	242	25 (10.3)	N.A.	229	10 (4.4)	N.A.	2.002 (0.947, 4.232) 0.0640	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9873
STAGE III	37	3 (8.1)	N.A.	24	0	N.E.	N.E. 0.2246	
STAGE IV	265	31 (11.7)	N.A.	262	14 (5.3)	N.A.	1.980 (1.044, 3.756) 0.0333	
PRIOR RADIOTHERAPY								0.1129
YES	26	2 (7.7)	N.A. (8.77, N.A.)	22	3 (13.6)	N.A.	0.282 (0.029, 2.716) 0.2423	
NO	278	32 (11.5)	N.A.	266	12 (4.5)	N.A.	2.339 (1.197, 4.572) 0.0105	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.8739
YES	88	11 (12.5)	N.A.	61	4 (6.6)	N.A.	1.745 (0.547, 5.565) 0.3406	
NO	216	23 (10.6)	N.A.	227	11 (4.8)	N.A.	1.951 (0.941, 4.046) 0.0676	
PD-L1 STATUS (IRT)								0.5076
>=1%	111	15 (13.5)	N.A.	101	5 (5.0)	N.A.	2.804 (1.019, 7.717) 0.0371	
<1%/INDETERMINATE	193	19 (9.8)	N.A.	187	10 (5.3)	N.A.	1.472 (0.668, 3.242) 0.3351	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Amylase Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.7013
YES	64	9 (14.1)	N.A.	61	5 (8.2)	N.A.	1.751 (0.587, 5.229) 0.3084	
NO	240	25 (10.4)	N.A.	227	10 (4.4)	N.A.	2.004 (0.948, 4.235) 0.0636	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	15 (4.9)	N.A.	288	1 (0.3)	N.A.	8.567 (1.099, 66.784) 0.0142	
PD-L1 STATUS								N.M.E.
>= 1%	112	8 (7.1)	N.M.E.	100	0	N.M.E.	N.M.E.	
< 1%	192	7 (3.6)	N.M.E.	188	1 (0.5)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								N.M.E.
< 65	150	7 (4.7)	N.M.E.	140	1 (0.7)	N.M.E.	N.M.E.	
>= 65 AND < 75	120	7 (5.8)	N.M.E.	111	0	N.M.E.	N.M.E.	
>= 75	34	1 (2.9)	N.M.E.	37	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9893
FEMALE	68	5 (7.4)	N.A.	65	1 (1.5)	N.A.	4.668 (0.545, 39.982) 0.1214	
MALE	236	10 (4.2)	N.A.	223	0	N.E.	N.E. 0.0503	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								>0.9999
WHITE	211	12 (5.7)	N.A.	214	1 (0.5)	N.A.	6.510 (0.807, 52.508) 0.0444	
ASIAN	75	3 (4.0)	N.A.	59	0	N.E.	N.E. 0.1506	
OTHER	17	0	N.E.	12	0	N.E.	N.E. N.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
US	19	0	N.M.E.	20	0	N.M.E.	N.M.E.	
ASIA	72	3 (4.2)	N.M.E.	57	0	N.M.E.	N.M.E.	
EUROPE	134	4 (3.0)	N.M.E.	134	0	N.M.E.	N.M.E.	
REST OF THE WORLD	79	8 (10.1)	N.M.E.	77	1 (1.3)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.9888
0	162	3 (1.9)	N.A.	155	1 (0.6)	N.A.	1.901 (0.174, 20.743) 0.5922	
1	140	12 (8.6)	N.A.	133	0	N.E.	N.E. 0.0098	
LIVER METASTASIS								0.9919
YES	62	4 (6.5)	N.A. (24.71, N.A.)	59	0	N.E.	N.E. 0.2028	
NO	242	11 (4.5)	N.A.	229	1 (0.4)	N.A.	6.780 (0.848, 54.194) 0.0374	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9996
STAGE III	37	0	N.E.	24	0	N.E.	N.E. N.E.	
STAGE IV	265	15 (5.7)	N.A.	262	1 (0.4)	N.A.	9.000 (1.154, 70.165) 0.0115	
PRIOR RADIOTHERAPY								0.9927
YES	26	2 (7.7)	N.A.	22	0	N.E.	N.E. 0.4126	
NO	278	13 (4.7)	N.A.	266	1 (0.4)	N.A.	7.615 (0.963, 60.226) 0.0237	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	88	8 (9.1)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	216	7 (3.2)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	
PD-L1 STATUS (IRT)								N.M.E.
>=1%	111	8 (7.2)	N.M.E.	101	0	N.M.E.	N.M.E.	
<1%/INDETERMINATE	193	7 (3.6)	N.M.E.	187	1 (0.5)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.9916
YES	64	4 (6.3)	N.A. (24.71, N.A.)	61	0	N.E.	N.E. 0.2079	
NO	240	11 (4.6)	N.A.	227	1 (0.4)	N.A.	6.802 (0.851, 54.357) 0.0369	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	94 (30.9)	N.A.	288	57 (19.8)	N.A.	1.484 (1.064, 2.071) 0.0187	
PD-L1 STATUS								0.4584
>= 1%	112	33 (29.5)	N.A.	100	22 (22.0)	N.A.	1.188 (0.684, 2.066) 0.5376	
< 1%	192	61 (31.8)	N.A.	188	35 (18.6)	N.A.	1.680 (1.106, 2.552) 0.0135	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.9805
< 65	150	49 (32.7)	N.A.	140	29 (20.7)	N.A.	1.539 (0.967, 2.448) 0.0655	
>= 65 AND < 75	120	36 (30.0)	N.A.	111	22 (19.8)	N.A.	1.380 (0.805, 2.366) 0.2356	
>= 75	34	9 (26.5)	N.A.	37	6 (16.2)	N.A.	1.573 (0.560, 4.420) 0.3862	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8346
FEMALE	68	19 (27.9)	N.A.	65	11 (16.9)	N.A.	1.612 (0.762, 3.409) 0.2052	
MALE	236	75 (31.8)	N.A.	223	46 (20.6)	N.A.	1.452 (1.001, 2.105) 0.0470	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.5362
WHITE	211	63 (29.9)	N.A.	214	37 (17.3)	N.A.	1.646 (1.090, 2.484) 0.0163	
ASIAN	75	26 (34.7)	N.A.	59	17 (28.8)	N.A.	1.120 (0.605, 2.074) 0.7081	
OTHER	17	5 (29.4)	N.A. (0.99, N.A.)	12	2 (16.7)	N.A. (0.07, N.A.)	1.674 (0.325, 8.637) 0.5335	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.7204
US	19	11 (57.9)	3.32 (0.66, N.A.)	20	5 (25.0)	N.A. (0.79, N.A.)	2.570 (0.891, 7.411) 0.0696	
ASIA	72	25 (34.7)	N.A. (9.69, N.A.)	57	15 (26.3)	N.A.	1.270 (0.666, 2.421) 0.4633	
EUROPE	134	32 (23.9)	N.A.	134	22 (16.4)	N.A.	1.273 (0.730, 2.222) 0.3932	
REST OF THE WORLD	79	26 (32.9)	N.A.	77	15 (19.5)	N.A.	1.600 (0.843, 3.036) 0.1417	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.7888
0	162	45 (27.8)	N.A.	155	26 (16.8)	N.A.	1.575 (0.966, 2.567) 0.0644	
1	140	49 (35.0)	N.A. (14.95, N.A.)	133	31 (23.3)	N.A.	1.426 (0.904, 2.247) 0.1243	
LIVER METASTASIS								0.2145
YES	62	13 (21.0)	N.A.	59	12 (20.3)	N.A.	0.973 (0.444, 2.133) 0.9494	
NO	242	81 (33.5)	N.A.	229	45 (19.7)	N.A.	1.623 (1.122, 2.348) 0.0092	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.8531
STAGE III	37	13 (35.1)	N.A. (4.53, N.A.)	24	5 (20.8)	N.A.	1.688 (0.602, 4.735) 0.3135	
STAGE IV	265	80 (30.2)	N.A.	262	51 (19.5)	N.A.	1.457 (1.020, 2.080) 0.0364	
PRIOR RADIOTHERAPY								0.2043
YES	26	9 (34.6)	N.A. (5.49, N.A.)	22	8 (36.4)	N.A. (0.95, N.A.)	0.827 (0.319, 2.145) 0.7071	
NO	278	85 (30.6)	N.A.	266	49 (18.4)	N.A.	1.583 (1.109, 2.260) 0.0104	

June 2023 DBL. Includes events reported from the first dose of study therapy.
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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.6430
YES	88	24 (27.3)	N.A.	61	9 (14.8)	N.A.	1.732 (0.797, 3.761) 0.1582	
NO	216	70 (32.4)	N.A.	227	48 (21.1)	N.A.	1.467 (1.012, 2.127) 0.0407	
PD-L1 STATUS (IRT)								0.4224
>=1%	111	32 (28.8)	N.A.	101	22 (21.8)	N.A.	1.167 (0.669, 2.038) 0.5834	
<1%/INDETERMINATE	193	62 (32.1)	N.A.	187	35 (18.7)	N.A.	1.694 (1.116, 2.569) 0.0118	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.1950
YES	64	14 (21.9)	N.A.	61	13 (21.3)	N.A.	0.978 (0.459, 2.080) 0.9572	
NO	240	80 (33.3)	N.A.	227	44 (19.4)	N.A.	1.633 (1.125, 2.371) 0.0090	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	21 (6.9)	N.A.	288	33 (11.5)	N.A.	0.548 (0.315, 0.954) 0.0309	
PD-L1 STATUS								0.2434
>= 1%	112	5 (4.5)	N.A.	100	12 (12.0)	N.A.	0.351 (0.124, 0.998) 0.0400	
< 1%	192	16 (8.3)	N.A.	188	21 (11.2)	N.A.	0.674 (0.348, 1.306) 0.2394	

June 2023 DBL. Includes events reported from the first dose of study therapy.
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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.1498
< 65	150	8 (5.3)	N.A.	140	15 (10.7)	N.A.	0.471 (0.200, 1.112) 0.0787	
>= 65 AND < 75	120	8 (6.7)	N.A.	111	16 (14.4)	N.A.	0.383 (0.158, 0.932) 0.0279	
>= 75	34	5 (14.7)	N.A.	37	2 (5.4)	N.A.	2.554 (0.495, 13.163) 0.2453	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3577
FEMALE	68	8 (11.8)	N.A.	65	9 (13.8)	N.A.	0.736 (0.274, 1.976) 0.5408	
MALE	236	13 (5.5)	N.A.	223	24 (10.8)	N.A.	0.482 (0.246, 0.947) 0.0305	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.8797
WHITE	211	17 (8.1)	N.A.	214	27 (12.6)	N.A.	0.603 (0.329, 1.107) 0.0989	
ASIAN	75	3 (4.0)	N.A.	59	4 (6.8)	N.A.	0.389 (0.071, 2.123) 0.2575	
OTHER	17	1 (5.9)	N.A.	12	2 (16.7)	N.A. (0.92, N.A.)	0.329 (0.030, 3.632) 0.3398	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.3901
US	19	2 (10.5)	N.A.	20	9 (45.0)	N.A. (0.95, N.A.)	0.201 (0.043, 0.931) 0.0224	
ASIA	72	3 (4.2)	N.A.	57	4 (7.0)	N.A.	0.390 (0.071, 2.130) 0.2595	
EUROPE	134	9 (6.7)	N.A.	134	9 (6.7)	N.A.	0.957 (0.380, 2.412) 0.9257	
REST OF THE WORLD	79	7 (8.9)	N.A.	77	11 (14.3)	N.A.	0.578 (0.224, 1.491) 0.2522	

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(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.8691
0	162	9 (5.6)	N.A.	155	14 (9.0)	N.A.	0.611 (0.265, 1.412) 0.2446	
1	140	12 (8.6)	N.A.	133	19 (14.3)	N.A.	0.502 (0.240, 1.052) 0.0631	
LIVER METASTASIS								0.3877
YES	62	3 (4.8)	N.A.	59	8 (13.6)	N.A.	0.339 (0.090, 1.277) 0.0931	
NO	242	18 (7.4)	N.A.	229	25 (10.9)	N.A.	0.614 (0.332, 1.137) 0.1174	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.6070
STAGE III	37	3 (8.1)	N.A.	24	2 (8.3)	N.A.	0.856 (0.142, 5.145) 0.8646	
STAGE IV	265	18 (6.8)	N.A.	262	31 (11.8)	N.A.	0.521 (0.289, 0.940) 0.0277	
PRIOR RADIOTHERAPY								0.6388
YES	26	2 (7.7)	N.A.	22	4 (18.2)	N.A.	0.403 (0.074, 2.200) 0.2773	
NO	278	19 (6.8)	N.A.	266	29 (10.9)	N.A.	0.568 (0.316, 1.021) 0.0558	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.4751
YES	88	4 (4.5)	N.A.	61	7 (11.5)	N.A.	0.386 (0.113, 1.318) 0.1145	
NO	216	17 (7.9)	N.A.	227	26 (11.5)	N.A.	0.613 (0.330, 1.141) 0.1195	
PD-L1 STATUS (IRT)								0.1817
>=1%	111	5 (4.5)	N.A.	101	13 (12.9)	N.A.	0.330 (0.118, 0.926) 0.0269	
<1%/INDETERMINATE	193	16 (8.3)	N.A.	187	20 (10.7)	N.A.	0.701 (0.359, 1.367) 0.2947	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.3850
YES	64	3 (4.7)	N.A.	61	8 (13.1)	N.A.	0.344 (0.091, 1.298) 0.0987	
NO	240	18 (7.5)	N.A.	227	25 (11.0)	N.A.	0.614 (0.332, 1.136) 0.1170	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	139 (45.7)	12.94 (7.85, N.A.)	288	61 (21.2)	N.A.	2.006 (1.477, 2.725) <0.0001	
PD-L1 STATUS								0.2349
>= 1%	112	52 (46.4)	9.00 (5.65, N.A.)	100	17 (17.0)	N.A.	2.656 (1.528, 4.620) 0.0003	
< 1%	192	87 (45.3)	13.37 (7.98, N.A.)	188	44 (23.4)	N.A.	1.753 (1.210, 2.538) 0.0026	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.2362
< 65	150	71 (47.3)	12.58 (7.82, N.A.)	140	26 (18.6)	N.A.	2.255 (1.425, 3.570) 0.0004	
>= 65 AND < 75	120	55 (45.8)	9.00 (6.11, N.A.)	111	31 (27.9)	N.A.	1.578 (1.011, 2.464) 0.0426	
>= 75	34	13 (38.2)	N.A. (5.52, N.A.)	37	4 (10.8)	N.A.	3.591 (1.159, 11.124) 0.0182	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1245
FEMALE	68	32 (47.1)	12.58 (5.26, N.A.)	65	20 (30.8)	N.A. (7.46, N.A.)	1.313 (0.738, 2.335) 0.3509	
MALE	236	107 (45.3)	13.37 (7.82, N.A.)	223	41 (18.4)	N.A.	2.341 (1.624, 3.373) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.3626
WHITE	211	85 (40.3)	17.87 (12.42, N.A.)	214	44 (20.6)	N.A.	1.607 (1.105, 2.338) 0.0122	
ASIAN	75	44 (58.7)	5.09 (2.04, 7.85)	59	15 (25.4)	N.A.	2.775 (1.540, 4.998) 0.0004	
OTHER	17	9 (52.9)	7.59 (0.72, N.A.)	12	2 (16.7)	N.A. (0.46, N.A.)	3.279 (0.700, 15.358) 0.1108	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.0481*
US	19	9 (47.4)	5.65 (2.00, N.A.)	20	9 (45.0)	N.A. (0.39, N.A.)	0.989 (0.391, 2.497) 0.9870	
ASIA	72	41 (56.9)	5.52 (2.60, 8.94)	57	15 (26.3)	N.A.	2.534 (1.399, 4.593) 0.0015	
EUROPE	134	59 (44.0)	13.37 (9.00, N.A.)	134	18 (13.4)	N.A.	2.785 (1.621, 4.786) 0.0001	
REST OF THE WORLD	79	30 (38.0)	N.A. (8.38, N.A.)	77	19 (24.7)	N.A.	1.269 (0.704, 2.285) 0.4255	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.6710
0	162	81 (50.0)	12.42 (5.62, N.A.)	155	35 (22.6)	N.A.	2.178 (1.454, 3.261) 0.0001	
1	140	57 (40.7)	14.03 (8.38, N.A.)	133	26 (19.5)	N.A.	1.783 (1.112, 2.859) 0.0149	
LIVER METASTASIS								0.9386
YES	62	28 (45.2)	8.94 (3.71, N.A.)	59	13 (22.0)	N.A.	1.989 (1.025, 3.857) 0.0377	
NO	242	111 (45.9)	14.03 (7.92, N.A.)	229	48 (21.0)	N.A.	2.009 (1.422, 2.838) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.6358
STAGE III	37	20 (54.1)	8.94 (2.10, N.A.)	24	5 (20.8)	N.A. (7.46, N.A.)	2.387 (0.879, 6.484) 0.0785	
STAGE IV	265	118 (44.5)	12.94 (7.85, N.A.)	262	54 (20.6)	N.A.	2.051 (1.479, 2.843) <0.0001	
PRIOR RADIOTHERAPY								0.6058
YES	26	10 (38.5)	17.87 (7.20, N.A.)	22	5 (22.7)	N.A.	1.367 (0.449, 4.163) 0.5793	
NO	278	129 (46.4)	12.58 (7.79, N.A.)	266	56 (21.1)	N.A.	2.075 (1.509, 2.854) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.3354
YES	88	42 (47.7)	12.94 (4.76, 18.63)	61	11 (18.0)	N.A.	2.530 (1.288, 4.970) 0.0053	
NO	216	97 (44.9)	12.58 (7.79, N.A.)	227	50 (22.0)	N.A.	1.857 (1.313, 2.627) 0.0004	
PD-L1 STATUS (IRT)								0.2747
>=1%	111	52 (46.8)	9.00 (5.65, N.A.)	101	18 (17.8)	N.A.	2.570 (1.495, 4.419) 0.0004	
<1%/INDETERMINATE	193	87 (45.1)	13.37 (7.98, N.A.)	187	43 (23.0)	N.A.	1.769 (1.218, 2.569) 0.0024	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.8165
YES	64	29 (45.3)	8.94 (5.09, N.A.)	61	14 (23.0)	N.A.	1.781 (0.932, 3.402) 0.0757	
NO	240	110 (45.8)	13.37 (7.85, N.A.)	227	47 (20.7)	N.A.	2.069 (1.461, 2.929) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	54 (17.8)	N.A.	288	10 (3.5)	N.A.	3.758 (1.883, 7.499) <0.0001	
PD-L1 STATUS								0.8212
>= 1%	112	21 (18.8)	N.A.	100	4 (4.0)	N.A.	3.570 (1.198, 10.636) 0.0148	
< 1%	192	33 (17.2)	N.A.	188	6 (3.2)	N.A.	3.853 (1.579, 9.403) 0.0015	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.8638
< 65	150	29 (19.3)	N.A.	140	7 (5.0)	N.A.	2.555 (1.082, 6.031) 0.0269	
>= 65 AND < 75	120	18 (15.0)	N.A. (24.38, N.A.)	111	3 (2.7)	N.A.	4.133 (1.189, 14.368) 0.0156	
>= 75	34	7 (20.6)	N.A.	37	0	N.E.	N.E. 0.0054	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5366
FEMALE	68	16 (23.5)	N.A. (17.02, N.A.)	65	4 (6.2)	N.A.	2.481 (0.788, 7.813) 0.1083	
MALE	236	38 (16.1)	N.A.	223	6 (2.7)	N.A.	4.580 (1.907, 10.997) 0.0002	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9977
WHITE	211	38 (18.0)	N.A.	214	9 (4.2)	N.A.	2.863 (1.348, 6.084) 0.0043	
ASIAN	75	11 (14.7)	N.A.	59	0	N.E.	N.E. 0.0056	
OTHER	17	5 (29.4)	N.A. (3.94, N.A.)	12	1 (8.3)	N.A.	3.213 (0.364, 28.373) 0.2676	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.1340
US	19	2 (10.5)	N.A.	20	2 (10.0)	N.A.	1.056 (0.149, 7.503) 0.9562	
ASIA	72	9 (12.5)	N.A.	57	0	N.E.	N.E. 0.0148	
EUROPE	134	26 (19.4)	N.A.	134	1 (0.7)	N.A.	17.756 (2.371,>99.999) 0.0001	
REST OF THE WORLD	79	17 (21.5)	N.A.	77	7 (9.1)	N.A.	1.645 (0.655, 4.128) 0.2849	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.9508
0	162	27 (16.7)	N.A.	155	5 (3.2)	N.A.	3.805 (1.427, 10.141) 0.0041	
1	140	26 (18.6)	N.A. (24.38, N.A.)	133	5 (3.8)	N.A.	3.562 (1.341, 9.465) 0.0067	
LIVER METASTASIS								0.8170
YES	62	8 (12.9)	N.A.	59	2 (3.4)	N.A.	2.899 (0.594, 14.150) 0.1695	
NO	242	46 (19.0)	N.A.	229	8 (3.5)	N.A.	3.948 (1.829, 8.519) 0.0002	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9871
STAGE III	37	8 (21.6)	N.A.	24	0	N.E.	N.E. 0.0407	
STAGE IV	265	46 (17.4)	N.A.	262	9 (3.4)	N.A.	3.647 (1.752, 7.592) 0.0002	
PRIOR RADIOTHERAPY								0.9810
YES	26	6 (23.1)	17.87 (9.82, N.A.)	22	0	N.E.	N.E. 0.1450	
NO	278	48 (17.3)	N.A.	266	10 (3.8)	N.A.	3.527 (1.758, 7.078) 0.0002	

June 2023 DBL. Includes events reported from the first dose of study therapy.
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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.8836
YES	88	16 (18.2)	N.A.	61	2 (3.3)	N.A.	3.778 (0.838, 17.038) 0.0633	
NO	216	38 (17.6)	N.A.	227	8 (3.5)	N.A.	3.749 (1.719, 8.178) 0.0004	
PD-L1 STATUS (IRT)								0.8666
>=1%	111	21 (18.9)	N.A.	101	4 (4.0)	N.A.	3.648 (1.225, 10.868) 0.0130	
<1%/INDETERMINATE	193	33 (17.1)	N.A.	187	6 (3.2)	N.A.	3.808 (1.560, 9.295) 0.0016	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.3939
YES	64	9 (14.1)	N.A. (17.87, N.A.)	61	3 (4.9)	N.A.	1.885 (0.480, 7.412) 0.3573	
NO	240	45 (18.8)	N.A.	227	7 (3.1)	N.A.	4.538 (2.014, 10.226) <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	52 (17.1)	N.A.	288	16 (5.6)	N.A.	2.469 (1.391, 4.382) 0.0014	
PD-L1 STATUS								0.6005
>= 1%	112	18 (16.1)	N.A.	100	4 (4.0)	N.A.	2.944 (0.971, 8.922) 0.0456	
< 1%	192	34 (17.7)	N.A.	188	12 (6.4)	N.A.	2.328 (1.189, 4.561) 0.0112	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.9621
< 65	150	26 (17.3)	N.A.	140	8 (5.7)	N.A.	2.404 (1.066, 5.419) 0.0290	
>= 65 AND < 75	120	21 (17.5)	N.A.	111	8 (7.2)	N.A.	2.039 (0.887, 4.686) 0.0866	
>= 75	34	5 (14.7)	N.A. (23.20, N.A.)	37	0	N.E.	N.E. 0.0577	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3491
FEMALE	68	8 (11.8)	N.A.	65	4 (6.2)	N.A.	1.547 (0.451, 5.305) 0.4846	
MALE	236	44 (18.6)	N.A.	223	12 (5.4)	N.A.	2.780 (1.448, 5.339) 0.0014	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.0514
WHITE	211	34 (16.1)	N.A.	214	13 (6.1)	N.A.	1.899 (0.976, 3.695) 0.0547	
ASIAN	75	16 (21.3)	N.A.	59	1 (1.7)	N.A.	12.366 (1.636, 93.468) 0.0018	
OTHER	17	1 (5.9)	N.A.	12	2 (16.7)	N.A. (0.46, N.A.)	0.317 (0.029, 3.509) 0.3232	

June 2023 DBL. Includes events reported from the first dose of study therapy.
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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.0563
US	19	2 (10.5)	N.A.	20	4 (20.0)	N.A.	0.508 (0.093, 2.777) 0.4306	
ASIA	72	16 (22.2)	N.A.	57	1 (1.8)	N.A.	12.390 (1.639, 93.668) 0.0017	
EUROPE	134	23 (17.2)	N.A.	134	5 (3.7)	N.A.	3.126 (1.150, 8.502) 0.0187	
REST OF THE WORLD	79	11 (13.9)	N.A. (24.71, N.A.)	77	6 (7.8)	N.A.	1.361 (0.484, 3.826) 0.5558	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.6233
0	162	33 (20.4)	N.A.	155	9 (5.8)	N.A.	3.068 (1.451, 6.485) 0.0020	
1	140	19 (13.6)	N.A. (24.71, N.A.)	133	7 (5.3)	N.A.	1.820 (0.737, 4.493) 0.1872	
LIVER METASTASIS								0.4715
YES	62	16 (25.8)	24.71 (12.94, N.A.)	59	7 (11.9)	N.A.	1.729 (0.695, 4.297) 0.2327	
NO	242	36 (14.9)	N.A.	229	9 (3.9)	N.A.	3.072 (1.459, 6.470) 0.0019	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.6784
STAGE III	37	7 (18.9)	N.A. (14.03, N.A.)	24	1 (4.2)	N.A.	3.170 (0.370, 27.154) 0.2661	
STAGE IV	265	44 (16.6)	N.A.	262	15 (5.7)	N.A.	2.415 (1.329, 4.390) 0.0028	
PRIOR RADIOTHERAPY								0.3142
YES	26	3 (11.5)	N.A.	22	2 (9.1)	N.A.	1.227 (0.205, 7.349) 0.8225	
NO	278	49 (17.6)	N.A.	266	14 (5.3)	N.A.	2.656 (1.446, 4.880) 0.0011	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.4891
YES	88	16 (18.2)	N.A.	61	5 (8.2)	N.A.	1.809 (0.645, 5.074) 0.2532	
NO	216	36 (16.7)	N.A.	227	11 (4.8)	N.A.	2.715 (1.361, 5.414) 0.0032	
PD-L1 STATUS (IRT)								0.5563
>=1%	111	18 (16.2)	N.A.	101	4 (4.0)	N.A.	3.010 (0.993, 9.123) 0.0409	
<1%/INDETERMINATE	193	34 (17.6)	N.A.	187	12 (6.4)	N.A.	2.301 (1.175, 4.508) 0.0124	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.4232
YES	64	16 (25.0)	24.71 (12.94, N.A.)	61	7 (11.5)	N.A.	1.707 (0.685, 4.252) 0.2449	
NO	240	36 (15.0)	N.A.	227	9 (4.0)	N.A.	3.077 (1.461, 6.480) 0.0019	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	13 (4.3)	N.A.	288	1 (0.3)	N.A.	10.811 (1.401, 83.397) 0.0043	
PD-L1 STATUS								0.9926
>= 1%	112	4 (3.6)	N.A.	100	0	N.E.	N.E. 0.0582	
< 1%	192	9 (4.7)	N.A.	188	1 (0.5)	N.A.	7.193 (0.894, 57.900) 0.0307	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								N.M.E.
< 65	150	5 (3.3)	N.M.E.	140	0	N.M.E.	N.M.E.	
>= 65 AND < 75	120	7 (5.8)	N.M.E.	111	0	N.M.E.	N.M.E.	
>= 75	34	1 (2.9)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9941
FEMALE	68	2 (2.9)	N.A.	65	0	N.E.	N.E. 0.1620	
MALE	236	11 (4.7)	N.A.	223	1 (0.4)	N.A.	8.796 (1.121, 69.032) 0.0127	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								N.M.E.
WHITE	211	6 (2.8)	N.M.E.	214	0	N.M.E.	N.M.E.	
ASIAN	75	4 (5.3)	N.M.E.	59	1 (1.7)	N.M.E.	N.M.E.	
OTHER	17	3 (17.6)	N.M.E.	12	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
US	19	2 (10.5)	N.M.E.	20	0	N.M.E.	N.M.E.	
ASIA	72	3 (4.2)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	
EUROPE	134	8 (6.0)	N.M.E.	134	0	N.M.E.	N.M.E.	
REST OF THE WORLD	79	0	N.M.E.	77	0	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								N.M.E.
0	162	7 (4.3)	N.M.E.	155	0	N.M.E.	N.M.E.	
1	140	6 (4.3)	N.M.E.	133	1 (0.8)	N.M.E.	N.M.E.	
LIVER METASTASIS								N.M.E.
YES	62	6 (9.7)	N.M.E.	59	0	N.M.E.	N.M.E.	
NO	242	7 (2.9)	N.M.E.	229	1 (0.4)	N.M.E.	N.M.E.	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9919
STAGE III	37	3 (8.1)	N.A.	24	0	N.E.	N.E. 0.1684	
STAGE IV	265	10 (3.8)	N.A.	262	1 (0.4)	N.A.	8.291 (1.045, 65.789) 0.0170	
PRIOR RADIOTHERAPY								0.9923
YES	26	2 (7.7)	N.A.	22	1 (4.5)	N.A.	1.785 (0.162, 19.703) 0.6313	
NO	278	11 (4.0)	N.A.	266	0	N.E.	N.E. 0.0029	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.9909
YES	88	4 (4.5)	N.A.	61	0	N.E.	N.E. 0.0916	
NO	216	9 (4.2)	N.A.	227	1 (0.4)	N.A.	7.749 (0.963, 62.342) 0.0233	
PD-L1 STATUS (IRT)								0.9926
>=1%	111	4 (3.6)	N.A.	101	0	N.E.	N.E. 0.0557	
<1%/INDETERMINATE	193	9 (4.7)	N.A.	187	1 (0.5)	N.A.	7.114 (0.884, 57.269) 0.0319	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								N.M.E.
YES	64	6 (9.4)	N.M.E.	61	0	N.M.E.	N.M.E.	
NO	240	7 (2.9)	N.M.E.	227	1 (0.4)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	125 (41.1)	N.A. (10.22, N.A.)	288	81 (28.1)	10.58 (10.58, N.A.)	1.385 (1.043, 1.837) 0.0235	
PD-L1 STATUS								0.3272
>= 1%	112	52 (46.4)	10.22 (5.72, N.A.)	100	28 (28.0)	N.A.	1.625 (1.019, 2.591) 0.0392	
< 1%	192	73 (38.0)	N.A. (15.44, N.A.)	188	53 (28.2)	10.58 (10.58, N.A.)	1.251 (0.875, 1.788) 0.2187	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.3012
< 65	150	66 (44.0)	N.A. (6.28, N.A.)	140	45 (32.1)	10.58 (10.58, N.A.)	1.371 (0.936, 2.010) 0.1045	
>= 65 AND < 75	120	50 (41.7)	N.A. (6.74, N.A.)	111	26 (23.4)	N.A.	1.701 (1.054, 2.746) 0.0272	
>= 75	34	9 (26.5)	N.A. (15.44, N.A.)	37	10 (27.0)	N.A. (5.52, N.A.)	0.682 (0.267, 1.738) 0.4213	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9854
FEMALE	68	28 (41.2)	N.A. (5.82, N.A.)	65	19 (29.2)	N.A.	1.346 (0.745, 2.433) 0.3242	
MALE	236	97 (41.1)	N.A. (10.22, N.A.)	223	62 (27.8)	10.58 (10.58, N.A.)	1.396 (1.011, 1.926) 0.0412	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.3411
WHITE	211	88 (41.7)	N.A. (7.10, N.A.)	214	67 (31.3)	10.58 (10.58, N.A.)	1.321 (0.960, 1.819) 0.0872	
ASIAN	75	27 (36.0)	N.A. (9.23, N.A.)	59	11 (18.6)	N.A.	1.488 (0.724, 3.057) 0.2728	
OTHER	17	10 (58.8)	7.20 (0.72, N.A.)	12	3 (25.0)	N.A. (5.52, N.A.)	2.896 (0.787, 10.661) 0.0946	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.6173
US	19	13 (68.4)	2.33 (0.30, 3.42)	20	12 (60.0)	2.20 (0.07, N.A.)	1.093 (0.498, 2.398) 0.8087	
ASIA	72	25 (34.7)	N.A. (9.23, N.A.)	57	9 (15.8)	N.A.	1.681 (0.769, 3.676) 0.1854	
EUROPE	134	60 (44.8)	N.A. (6.41, N.A.)	134	39 (29.1)	N.A.	1.600 (1.066, 2.401) 0.0223	
REST OF THE WORLD	79	27 (34.2)	N.A.	77	21 (27.3)	N.A.	1.196 (0.676, 2.116) 0.5396	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.3198
0	162	71 (43.8)	N.A. (7.36, N.A.)	155	41 (26.5)	10.58 (N.A., N.A.)	1.516 (1.025, 2.242) 0.0356	
1	140	53 (37.9)	N.A. (9.23, N.A.)	133	40 (30.1)	N.A.	1.239 (0.820, 1.871) 0.3102	
LIVER METASTASIS								0.4179
YES	62	22 (35.5)	N.A. (6.77, N.A.)	59	12 (20.3)	10.58 (10.58, N.A.)	1.855 (0.915, 3.761) 0.0819	
NO	242	103 (42.6)	N.A. (8.64, N.A.)	229	69 (30.1)	N.A.	1.306 (0.959, 1.779) 0.0888	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7491
STAGE III	37	15 (40.5)	N.A. (2.23, N.A.)	24	6 (25.0)	N.A. (4.93, N.A.)	1.673 (0.649, 4.317) 0.2814	
STAGE IV	265	109 (41.1)	N.A. (10.22, N.A.)	262	74 (28.2)	10.58 (10.58, N.A.)	1.361 (1.009, 1.836) 0.0425	
PRIOR RADIOTHERAPY								0.8316
YES	26	13 (50.0)	5.65 (1.58, N.A.)	22	7 (31.8)	N.A. (1.38, N.A.)	1.527 (0.609, 3.829) 0.3612	
NO	278	112 (40.3)	N.A. (10.51, N.A.)	266	74 (27.8)	10.58 (10.58, N.A.)	1.360 (1.010, 1.831) 0.0422	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.9265
YES	88	37 (42.0)	N.A. (5.52, N.A.)	61	18 (29.5)	N.A.	1.427 (0.807, 2.523) 0.2181	
NO	216	88 (40.7)	N.A. (8.64, N.A.)	227	63 (27.8)	10.58 (10.58, N.A.)	1.362 (0.982, 1.889) 0.0632	
PD-L1 STATUS (IRT)								0.3809
>=1%	111	52 (46.8)	10.22 (5.72, N.A.)	101	29 (28.7)	N.A.	1.589 (1.002, 2.520) 0.0468	
<1%/INDETERMINATE	193	73 (37.8)	N.A. (15.44, N.A.)	187	52 (27.8)	10.58 (10.58, N.A.)	1.266 (0.884, 1.813) 0.1979	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.7381
YES	64	21 (32.8)	N.A.	61	13 (21.3)	10.58 (10.58, N.A.)	1.597 (0.797, 3.203) 0.1836	
NO	240	104 (43.3)	N.A. (7.56, N.A.)	227	68 (30.0)	N.A.	1.346 (0.988, 1.835) 0.0583	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	31 (10.2)	N.A.	288	15 (5.2)	N.A.	1.867 (1.002, 3.479) 0.0460	
PD-L1 STATUS								0.8155
>= 1%	112	12 (10.7)	N.A.	100	6 (6.0)	N.A.	1.695 (0.629, 4.571) 0.2920	
< 1%	192	19 (9.9)	N.A.	188	9 (4.8)	N.A.	1.979 (0.890, 4.404) 0.0884	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.1647
< 65	150	19 (12.7)	N.A.	140	5 (3.6)	N.A.	3.526 (1.309, 9.494) 0.0078	
>= 65 AND < 75	120	11 (9.2)	N.A.	111	8 (7.2)	N.A.	1.171 (0.464, 2.956) 0.7382	
>= 75	34	1 (2.9)	N.A.	37	2 (5.4)	N.A.	0.524 (0.048, 5.785) 0.5918	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

Subgroup	Nivolumab + SOC N	Nivolumab + SOC Subjects with Event n (%)	Nivolumab + SOC KME (95%CI)(mon) (1)	SOC N	SOC Subjects with Event n (%)	SOC KME (95%CI)(mon) (1)	Nivolumab + SOC vs. SOC HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1965
FEMALE	68	5 (7.4)	N.A.	65	5 (7.7)	N.A.	0.986 (0.285, 3.408) 0.9826	
MALE	236	26 (11.0)	N.A.	223	10 (4.5)	N.A.	2.310 (1.106, 4.827) 0.0220	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9709
WHITE	211	23 (10.9)	N.A.	214	12 (5.6)	N.A.	1.970 (0.980, 3.960) 0.0525	
ASIAN	75	6 (8.0)	N.A.	59	3 (5.1)	N.A.	1.383 (0.333, 5.740) 0.6538	
OTHER	17	2 (11.8)	N.A. (17.18, N.A.)	12	0	N.E.	N.E. 0.3865	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
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subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.7142
US	19	2 (10.5)	N.A.	20	2 (10.0)	N.A.	1.040 (0.146, 7.389) 0.9686	
ASIA	72	5 (6.9)	N.A.	57	3 (5.3)	N.A.	1.103 (0.249, 4.894) 0.8972	
EUROPE	134	15 (11.2)	N.A.	134	5 (3.7)	N.A.	2.859 (1.030, 7.940) 0.0349	
REST OF THE WORLD	79	9 (11.4)	N.A.	77	5 (6.5)	N.A.	1.758 (0.589, 5.247) 0.3060	

June 2023 DBL. Includes events reported from the first dose of study therapy.
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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.0294*
0	162	17 (10.5)	N.A.	155	3 (1.9)	N.A.	5.012 (1.453, 17.292) 0.0046	
1	140	14 (10.0)	N.A.	133	12 (9.0)	N.A.	1.089 (0.503, 2.355) 0.8303	
LIVER METASTASIS								0.7236
YES	62	3 (4.8)	N.A.	59	1 (1.7)	N.A.	2.926 (0.304, 28.135) 0.3305	
NO	242	28 (11.6)	N.A.	229	14 (6.1)	N.A.	1.797 (0.939, 3.440) 0.0727	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.6474
STAGE III	37	8 (21.6)	N.A.	24	2 (8.3)	N.A.	2.568 (0.545, 12.110) 0.2176	
STAGE IV	265	23 (8.7)	N.A.	262	13 (5.0)	N.A.	1.634 (0.819, 3.260) 0.1594	
PRIOR RADIOTHERAPY								0.6422
YES	26	3 (11.5)	N.A.	22	2 (9.1)	N.A.	1.281 (0.213, 7.691) 0.7862	
NO	278	28 (10.1)	N.A.	266	13 (4.9)	N.A.	1.954 (1.005, 3.799) 0.0444	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.1110
YES	88	8 (9.1)	N.A.	61	6 (9.8)	N.A.	0.954 (0.331, 2.748) 0.9288	
NO	216	23 (10.6)	N.A.	227	9 (4.0)	N.A.	2.489 (1.141, 5.428) 0.0177	
PD-L1 STATUS (IRT)								0.8567
>=1%	111	12 (10.8)	N.A.	101	6 (5.9)	N.A.	1.731 (0.642, 4.667) 0.2730	
<1%/INDETERMINATE	193	19 (9.8)	N.A.	187	9 (4.8)	N.A.	1.957 (0.880, 4.354) 0.0940	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Nervous System Disorders. PT: Headache

Subgroup	Nivolumab + SOC N	Nivolumab + SOC Subjects with Event n (%)	Nivolumab + SOC KME (95%CI)(mon) (1)	SOC N	SOC Subjects with Event n (%)	SOC KME (95%CI)(mon) (1)	Nivolumab + SOC vs. SOC HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.4511
YES	64	2 (3.1)	N.A.	61	2 (3.3)	N.A.	0.945 (0.133, 6.710) 0.9515	
NO	240	29 (12.1)	N.A.	227	13 (5.7)	N.A.	2.014 (1.040, 3.901) 0.0342	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	17 (5.6)	N.A.	288	5 (1.7)	N.A.	2.696 (0.978, 7.431) 0.0462	
PD-L1 STATUS								0.5482
>= 1%	112	8 (7.1)	N.A.	100	3 (3.0)	N.A.	1.815 (0.464, 7.102) 0.3851	
< 1%	192	9 (4.7)	N.A.	188	2 (1.1)	N.A.	3.971 (0.848, 18.602) 0.0589	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.4123
< 65	150	8 (5.3)	N.A.	140	1 (0.7)	N.A.	5.584 (0.680, 45.854) 0.0722	
>= 65 AND < 75	120	6 (5.0)	N.A.	111	4 (3.6)	N.A.	1.230 (0.337, 4.483) 0.7538	
>= 75	34	3 (8.8)	N.A.	37	0	N.E.	N.E. 0.0823	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3116
FEMALE	68	3 (4.4)	N.A.	65	2 (3.1)	N.A.	1.092 (0.172, 6.930) 0.9259	
MALE	236	14 (5.9)	N.A.	223	3 (1.3)	N.A.	3.774 (1.069, 13.331) 0.0268	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								>0.9999
WHITE	211	12 (5.7)	N.A.	214	5 (2.3)	N.A.	2.073 (0.714, 6.018) 0.1708	
ASIAN	75	4 (5.3)	N.A.	59	0	N.E.	N.E. 0.1342	
OTHER	17	1 (5.9)	N.A.	12	0	N.E.	N.E. 0.4070	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
US	19	2 (10.5)	N.M.E.	20	1 (5.0)	N.M.E.	N.M.E.	
ASIA	72	3 (4.2)	N.M.E.	57	0	N.M.E.	N.M.E.	
EUROPE	134	8 (6.0)	N.M.E.	134	1 (0.7)	N.M.E.	N.M.E.	
REST OF THE WORLD	79	4 (5.1)	N.M.E.	77	3 (3.9)	N.M.E.	N.M.E.	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.6302
0	162	9 (5.6)	N.A.	155	2 (1.3)	N.A.	2.964 (0.608, 14.443) 0.1593	
1	140	8 (5.7)	N.A.	133	3 (2.3)	N.A.	2.477 (0.657, 9.339) 0.1658	
LIVER METASTASIS								0.6908
YES	62	2 (3.2)	N.A.	59	1 (1.7)	N.A.	1.948 (0.177, 21.491) 0.5793	
NO	242	15 (6.2)	N.A.	229	4 (1.7)	N.A.	2.861 (0.929, 8.805) 0.0556	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9922
STAGE III	37	1 (2.7)	N.A.	24	0	N.E.	N.E. 0.4344	
STAGE IV	265	16 (6.0)	N.A.	262	5 (1.9)	N.A.	2.620 (0.942, 7.290) 0.0557	
PRIOR RADIOTHERAPY								0.9996
YES	26	0	N.E.	22	0	N.E.	N.E. N.E.	
NO	278	17 (6.1)	N.A.	266	5 (1.9)	N.A.	2.731 (0.991, 7.526) 0.0432	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.9913
YES	88	5 (5.7)	N.A.	61	0	N.E.	N.E. 0.1348	
NO	216	12 (5.6)	N.A.	227	5 (2.2)	N.A.	2.259 (0.786, 6.495) 0.1200	
PD-L1 STATUS (IRT)								0.1968
>=1%	111	8 (7.2)	N.A.	101	4 (4.0)	N.A.	1.396 (0.404, 4.824) 0.5968	
<1%/INDETERMINATE	193	9 (4.7)	N.A.	187	1 (0.5)	N.A.	7.846 (0.985, 62.501) 0.0214	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.0453*
YES	64	2 (3.1)	N.A.	61	3 (4.9)	N.A.	0.644 (0.108, 3.856) 0.6272	
NO	240	15 (6.3)	N.A.	227	2 (0.9)	N.A.	5.724 (1.288, 25.441) 0.0097	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	101 (33.2)	47.51 (N.A., N.A.)	288	63 (21.9)	N.A.	1.393 (1.010, 1.922) 0.0431	
PD-L1 STATUS								0.5781
>= 1%	112	37 (33.0)	N.A. (22.64, N.A.)	100	24 (24.0)	N.A.	1.158 (0.679, 1.977) 0.5909	
< 1%	192	64 (33.3)	47.51 (N.A., N.A.)	188	39 (20.7)	N.A.	1.547 (1.033, 2.317) 0.0335	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.6996
< 65	150	50 (33.3)	47.51 (N.A., N.A.)	140	27 (19.3)	N.A.	1.623 (1.007, 2.616) 0.0448	
>= 65 AND < 75	120	40 (33.3)	N.A. (17.71, N.A.)	111	26 (23.4)	N.A.	1.230 (0.738, 2.048) 0.4296	
>= 75	34	11 (32.4)	N.A. (2.63, N.A.)	37	10 (27.0)	N.A.	1.204 (0.511, 2.835) 0.6708	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7457
FEMALE	68	21 (30.9)	N.A. (17.71, N.A.)	65	15 (23.1)	N.A.	1.179 (0.593, 2.343) 0.6404	
MALE	236	80 (33.9)	47.51 (25.00, N.A.)	223	48 (21.5)	N.A.	1.459 (1.013, 2.102) 0.0418	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.8942
WHITE	211	72 (34.1)	47.51 (N.A., N.A.)	214	49 (22.9)	N.A.	1.332 (0.917, 1.933) 0.1319	
ASIAN	75	22 (29.3)	N.A.	59	11 (18.6)	N.A.	1.592 (0.766, 3.309) 0.2107	
OTHER	17	7 (41.2)	25.00 (3.32, N.A.)	12	3 (25.0)	N.A. (0.92, N.A.)	1.311 (0.328, 5.243) 0.7012	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8639
US	19	13 (68.4)	2.10 (0.23, N.A.)	20	9 (45.0)	N.A. (1.41, N.A.)	1.999 (0.852, 4.692) 0.1056	
ASIA	72	20 (27.8)	N.A.	57	11 (19.3)	N.A.	1.418 (0.672, 2.989) 0.3603	
EUROPE	134	42 (31.3)	N.A. (25.00, N.A.)	134	28 (20.9)	N.A.	1.283 (0.784, 2.101) 0.3200	
REST OF THE WORLD	79	26 (32.9)	47.51 (N.A., N.A.)	77	15 (19.5)	N.A.	1.436 (0.746, 2.764) 0.2742	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.2589
0	162	62 (38.3)	N.A. (22.64, N.A.)	155	34 (21.9)	N.A.	1.648 (1.076, 2.525) 0.0204	
1	140	38 (27.1)	47.51 (N.A., N.A.)	133	29 (21.8)	N.A.	1.099 (0.668, 1.808) 0.7156	
LIVER METASTASIS								0.2654
YES	62	16 (25.8)	47.51 (N.A., N.A.)	59	14 (23.7)	N.A.	0.994 (0.477, 2.068) 0.9840	
NO	242	85 (35.1)	N.A. (25.00, N.A.)	229	49 (21.4)	N.A.	1.508 (1.053, 2.160) 0.0244	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.6334
STAGE III	37	17 (45.9)	10.61 (2.23, N.A.)	24	6 (25.0)	N.A. (4.40, N.A.)	1.581 (0.610, 4.097) 0.3442	
STAGE IV	265	84 (31.7)	47.51 (25.00, N.A.)	262	57 (21.8)	N.A.	1.341 (0.951, 1.892) 0.0943	
PRIOR RADIOTHERAPY								0.3435
YES	26	13 (50.0)	3.84 (1.68, N.A.)	22	6 (27.3)	N.A. (6.31, N.A.)	2.317 (0.878, 6.116) 0.0804	
NO	278	88 (31.7)	47.51 (N.A., N.A.)	266	57 (21.4)	N.A.	1.310 (0.930, 1.844) 0.1231	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.7949
YES	88	28 (31.8)	N.A. (17.71, N.A.)	61	14 (23.0)	N.A.	1.277 (0.663, 2.459) 0.4658	
NO	216	73 (33.8)	47.51 (25.00, N.A.)	227	49 (21.6)	N.A.	1.431 (0.988, 2.073) 0.0569	
PD-L1 STATUS (IRT)								0.3992
>=1%	111	36 (32.4)	N.A. (22.64, N.A.)	101	25 (24.8)	N.A.	1.092 (0.641, 1.859) 0.7483	
<1%/INDETERMINATE	193	65 (33.7)	47.51 (N.A., N.A.)	187	38 (20.3)	N.A.	1.604 (1.069, 2.407) 0.0218	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Respiratory, Thoracic and Mediastinal Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.3540
YES	64	17 (26.6)	47.51 (N.A., N.A.)	61	14 (23.0)	N.A.	1.071 (0.520, 2.206) 0.8548	
NO	240	84 (35.0)	N.A. (25.00, N.A.)	227	49 (21.6)	N.A.	1.484 (1.035, 2.127) 0.0311	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	20 (6.6)	N.A.	288	6 (2.1)	N.A.	2.517 (0.987, 6.417) 0.0455	
PD-L1 STATUS								0.3032
>= 1%	112	9 (8.0)	N.A.	100	4 (4.0)	N.A.	1.756 (0.529, 5.833) 0.3513	
< 1%	192	11 (5.7)	N.A.	188	2 (1.1)	N.A.	3.924 (0.837, 18.401) 0.0617	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.9930
< 65	150	7 (4.7)	N.A.	140	2 (1.4)	N.A.	2.767 (0.559, 13.691) 0.1930	
>= 65 AND < 75	120	12 (10.0)	N.A.	111	4 (3.6)	N.A.	2.086 (0.642, 6.775) 0.2108	
>= 75	34	1 (2.9)	N.A.	37	0	N.E.	N.E. 0.3103	

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(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8443
FEMALE	68	4 (5.9)	N.A.	65	1 (1.5)	N.A.	0.990 (0.066, 14.815) 0.9943	
MALE	236	16 (6.8)	N.A.	223	5 (2.2)	N.A.	2.804 (1.020, 7.711) 0.0369	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9971
WHITE	211	13 (6.2)	N.A.	214	5 (2.3)	N.A.	2.425 (0.856, 6.875) 0.0853	
ASIAN	75	3 (4.0)	N.A.	59	1 (1.7)	N.A.	1.433 (0.129, 15.912) 0.7684	
OTHER	17	4 (23.5)	N.A. (11.70, N.A.)	12	0	N.E.	N.E. 0.2132	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8607
US	19	5 (26.3)	N.A. (5.65, N.A.)	20	5 (25.0)	N.A. (2.53, N.A.)	1.102 (0.319, 3.810) 0.8777	
ASIA	72	3 (4.2)	N.A.	57	0	N.E.	N.E. 0.2418	
EUROPE	134	8 (6.0)	N.A.	134	0	N.E.	N.E. 0.0251	
REST OF THE WORLD	79	4 (5.1)	N.A.	77	1 (1.3)	N.A.	3.837 (0.429, 34.333) 0.1952	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.2677
0	162	12 (7.4)	N.A.	155	2 (1.3)	N.A.	4.804 (1.053, 21.909) 0.0251	
1	140	8 (5.7)	N.A.	133	4 (3.0)	N.A.	1.406 (0.401, 4.936) 0.5937	
LIVER METASTASIS								0.7687
YES	62	4 (6.5)	N.A.	59	1 (1.7)	N.A.	3.800 (0.425, 33.995) 0.1989	
NO	242	16 (6.6)	N.A.	229	5 (2.2)	N.A.	2.240 (0.791, 6.345) 0.1192	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9919
STAGE III	37	1 (2.7)	N.A.	24	0	N.E.	N.E. 0.4212	
STAGE IV	265	19 (7.2)	N.A.	262	6 (2.3)	N.A.	2.475 (0.963, 6.363) 0.0518	
PRIOR RADIOTHERAPY								0.3627
YES	26	1 (3.8)	N.A.	22	1 (4.5)	N.A.	0.863 (0.054, 13.798) 0.9169	
NO	278	19 (6.8)	N.A.	266	5 (1.9)	N.A.	2.858 (1.041, 7.847) 0.0331	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.5890
YES	88	6 (6.8)	N.A.	61	2 (3.3)	N.A.	2.116 (0.427, 10.486) 0.3474	
NO	216	14 (6.5)	N.A.	227	4 (1.8)	N.A.	2.591 (0.817, 8.215) 0.0937	
PD-L1 STATUS (IRT)								0.3210
>=1%	111	9 (8.1)	N.A.	101	4 (4.0)	N.A.	1.793 (0.540, 5.957) 0.3331	
<1%/INDETERMINATE	193	11 (5.7)	N.A.	187	2 (1.1)	N.A.	3.880 (0.828, 18.196) 0.0642	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Vascular Disorders. PT: Hypotension

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.7807
YES	64	4 (6.3)	N.A.	61	1 (1.6)	N.A.	3.806 (0.425, 34.053) 0.1983	
NO	240	16 (6.7)	N.A.	227	5 (2.2)	N.A.	2.241 (0.791, 6.347) 0.1190	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	59 (19.4)	N.A.	288	0	N.E.	N.E. <0.0001	
PD-L1 STATUS								0.9998
>= 1%	112	25 (22.3)	N.A.	100	0	N.E.	N.E. <0.0001	
< 1%	192	34 (17.7)	N.A.	188	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								>0.9999
< 65	150	33 (22.0)	N.A.	140	0	N.E.	N.E. <0.0001	
>= 65 AND < 75	120	21 (17.5)	N.A.	111	0	N.E.	N.E. <0.0001	
>= 75	34	5 (14.7)	N.A.	37	0	N.E.	N.E. 0.0214	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								>0.9999
FEMALE	68	11 (16.2)	N.A.	65	0	N.E.	N.E. 0.0016	
MALE	236	48 (20.3)	N.A.	223	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

Subgroup	Nivolumab + SOC N	Nivolumab + SOC Subjects with Event n (%)	Nivolumab + SOC KME (95%CI)(mon) (1)	SOC N	SOC Subjects with Event n (%)	SOC KME (95%CI)(mon) (1)	Nivolumab + SOC vs. SOC HR (95%CI) P-value (2)(3)	Nivolumab + SOC vs. SOC Test for Interaction P-value (4)(5)
RACE								>0.9999
WHITE	211	38 (18.0)	N.A.	214	0	N.E.	N.E. <0.0001	
ASIAN	75	17 (22.7)	N.A.	59	0	N.E.	N.E. 0.0014	
OTHER	17	4 (23.5)	N.A. (4.44, N.A.)	12	0	N.E.	N.E. 0.0714	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
US	19	4 (21.1)	N.A. (6.60, N.A.)	20	0	N.E.	N.E. 0.0218	
ASIA	72	16 (22.2)	N.A.	57	0	N.E.	N.E. 0.0024	
EUROPE	134	21 (15.7)	N.A.	134	0	N.E.	N.E. <0.0001	
REST OF THE WORLD	79	18 (22.8)	N.A.	77	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								>0.9999
0	162	36 (22.2)	N.A.	155	0	N.E.	N.E. <0.0001	
1	140	23 (16.4)	N.A.	133	0	N.E.	N.E. <0.0001	
LIVER METASTASIS								0.9998
YES	62	16 (25.8)	N.A.	59	0	N.E.	N.E. <0.0001	
NO	242	43 (17.8)	N.A.	229	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

Subgroup	Nivolumab + SOC N	Nivolumab + SOC Subjects with Event n (%)	Nivolumab + SOC KME (95%CI)(mon) (1)	SOC N	SOC Subjects with Event n (%)	SOC KME (95%CI)(mon) (1)	Nivolumab + SOC vs. SOC HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9999
STAGE III	37	10 (27.0)	N.A. (14.42, N.A.)	24	0	N.E.	N.E. 0.0333	
STAGE IV	265	49 (18.5)	N.A.	262	0	N.E.	N.E. <0.0001	
PRIOR RADIOTHERAPY								0.9997
YES	26	2 (7.7)	N.A.	22	0	N.E.	N.E. 0.2027	
NO	278	57 (20.5)	N.A.	266	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								>0.9999
YES	88	15 (17.0)	N.A.	61	0	N.E.	N.E. 0.0029	
NO	216	44 (20.4)	N.A.	227	0	N.E.	N.E. <0.0001	
PD-L1 STATUS (IRT)								0.9998
>=1%	111	25 (22.5)	N.A.	101	0	N.E.	N.E. <0.0001	
<1%/INDETERMINATE	193	34 (17.6)	N.A.	187	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.9998
YES	64	16 (25.0)	N.A.	61	0	N.E.	N.E. <0.0001	
NO	240	43 (17.9)	N.A.	227	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	41 (13.5)	N.A.	288	0	N.E.	N.E. <0.0001	
PD-L1 STATUS								0.9999
>= 1%	112	18 (16.1)	N.A.	100	0	N.E.	N.E. 0.0007	
< 1%	192	23 (12.0)	N.A.	188	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
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by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								>0.9999
< 65	150	23 (15.3)	N.A.	140	0	N.E.	N.E. 0.0001	
>= 65 AND < 75	120	15 (12.5)	N.A.	111	0	N.E.	N.E. 0.0003	
>= 75	34	3 (8.8)	N.A.	37	0	N.E.	N.E. 0.0854	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9998
FEMALE	68	6 (8.8)	N.A.	65	0	N.E.	N.E. 0.0302	
MALE	236	35 (14.8)	N.A.	223	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

Subgroup	Nivolumab + SOC N	Nivolumab + SOC Subjects with Event n (%)	Nivolumab + SOC KME (95%CI)(mon) (1)	SOC N	SOC Subjects with Event n (%)	SOC KME (95%CI)(mon) (1)	Nivolumab + SOC vs. SOC HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								>0.9999
WHITE	211	30 (14.2)	N.A.	214	0	N.E.	N.E. <0.0001	
ASIAN	75	8 (10.7)	N.A.	59	0	N.E.	N.E. 0.0282	
OTHER	17	3 (17.6)	N.A.	12	0	N.E.	N.E. 0.1389	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
US	19	3 (15.8)	N.A. (5.98, N.A.)	20	0	N.E.	N.E. 0.0560	
ASIA	72	7 (9.7)	N.A.	57	0	N.E.	N.E. 0.0430	
EUROPE	134	16 (11.9)	N.A.	134	0	N.E.	N.E. 0.0012	
REST OF THE WORLD	79	15 (19.0)	N.A.	77	0	N.E.	N.E. 0.0003	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.9999
0	162	21 (13.0)	N.A.	155	0	N.E.	N.E. 0.0002	
1	140	20 (14.3)	N.A.	133	0	N.E.	N.E. <0.0001	
LIVER METASTASIS								0.9998
YES	62	11 (17.7)	N.A.	59	0	N.E.	N.E. 0.0017	
NO	242	30 (12.4)	N.A.	229	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE III	37	7 (18.9)	N.A. (14.42, N.A.)	24	0	N.E.	N.E. 0.0922	
STAGE IV	265	34 (12.8)	N.A.	262	0	N.E.	N.E. <0.0001	
PRIOR RADIOTHERAPY								0.9997
YES	26	1 (3.8)	N.A.	22	0	N.E.	N.E. 0.3980	
NO	278	40 (14.4)	N.A.	266	0	N.E.	N.E. <0.0001	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								>0.9999
YES	88	11 (12.5)	N.A.	61	0	N.E.	N.E. 0.0209	
NO	216	30 (13.9)	N.A.	227	0	N.E.	N.E. <0.0001	
PD-L1 STATUS (IRT)								0.9998
>=1%	111	18 (16.2)	N.A.	101	0	N.E.	N.E. 0.0006	
<1%/INDETERMINATE	193	23 (11.9)	N.A.	187	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hypothyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.9998
YES	64	11 (17.2)	N.A.	61	0	N.E.	N.E. 0.0019	
NO	240	30 (12.5)	N.A.	227	0	N.E.	N.E. <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	22 (7.2)	N.A.	288	0	N.E.	N.E. <0.0001	
PD-L1 STATUS								>0.9999
>= 1%	112	9 (8.0)	N.A.	100	0	N.E.	N.E. 0.0071	
< 1%	192	13 (6.8)	N.A.	188	0	N.E.	N.E. 0.0005	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								>0.9999
< 65	150	13 (8.7)	N.A.	140	0	N.E.	N.E. 0.0011	
>= 65 AND < 75	120	6 (5.0)	N.A.	111	0	N.E.	N.E. 0.0178	
>= 75	34	3 (8.8)	N.A.	37	0	N.E.	N.E. 0.0801	

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(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
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(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								>0.9999
FEMALE	68	6 (8.8)	N.A.	65	0	N.E.	N.E. 0.0151	
MALE	236	16 (6.8)	N.A.	223	0	N.E.	N.E. 0.0002	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								>0.9999
WHITE	211	14 (6.6)	N.A.	214	0	N.E.	N.E. 0.0002	
ASIAN	75	6 (8.0)	N.A.	59	0	N.E.	N.E. 0.0498	
OTHER	17	2 (11.8)	N.A.	12	0	N.E.	N.E. 0.2233	

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Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
US	19	2 (10.5)	N.A.	20	0	N.E.	N.E. 0.1341	
ASIA	72	5 (6.9)	N.A.	57	0	N.E.	N.E. 0.0841	
EUROPE	134	11 (8.2)	N.A.	134	0	N.E.	N.E. 0.0013	
REST OF THE WORLD	79	4 (5.1)	N.A.	77	0	N.E.	N.E. 0.0492	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.9998
0	162	16 (9.9)	N.A.	155	0	N.E.	N.E. 0.0001	
1	140	6 (4.3)	N.A.	133	0	N.E.	N.E. 0.0223	
LIVER METASTASIS								0.9999
YES	62	6 (9.7)	N.A.	59	0	N.E.	N.E. 0.0177	
NO	242	16 (6.6)	N.A.	229	0	N.E.	N.E. 0.0002	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE III	37	4 (10.8)	N.A.	24	0	N.E.	N.E. 0.1223	
STAGE IV	265	18 (6.8)	N.A.	262	0	N.E.	N.E. <0.0001	
PRIOR RADIOTHERAPY								0.9999
YES	26	1 (3.8)	N.A.	22	0	N.E.	N.E. 0.3496	
NO	278	21 (7.6)	N.A.	266	0	N.E.	N.E. <0.0001	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								>0.9999
YES	88	7 (8.0)	N.A.	61	0	N.E.	N.E. 0.0262	
NO	216	15 (6.9)	N.A.	227	0	N.E.	N.E. 0.0002	
PD-L1 STATUS (IRT)								>0.9999
>=1%	111	9 (8.1)	N.A.	101	0	N.E.	N.E. 0.0065	
<1%/INDETERMINATE	193	13 (6.7)	N.A.	187	0	N.E.	N.E. 0.0005	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.1
Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Endocrine Disorders. PT: Hyperthyroidism

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.9999
YES	64	6 (9.4)	N.A.	61	0	N.E.	N.E. 0.0180	
NO	240	16 (6.7)	N.A.	227	0	N.E.	N.E. 0.0002	

June 2023 DBL. Includes events reported from the first dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 13MAR2024:13:15:05

Anhang 4-G-1.4.2.4.2: Subgruppenanalysen für häufige schwere UE auf SOC/PT-Ebene

Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	304	31 (10.2)	N.A.	288	11 (3.8)	N.A.	2.749 (1.381, 5.468) 0.0027	
PD-L1 STATUS								0.2438
>= 1%	112	9 (8.0)	N.A.	100	1 (1.0)	N.A.	8.185 (1.037, 64.605) 0.0172	
< 1%	192	22 (11.5)	N.A.	188	10 (5.3)	N.A.	2.227 (1.055, 4.704) 0.0313	

June 2023 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
AGE CATEGORIZATION								0.1525
< 65	150	10 (6.7)	N.A.	140	7 (5.0)	N.A.	1.356 (0.516, 3.562) 0.5373	
>= 65 AND < 75	120	19 (15.8)	N.A.	111	3 (2.7)	N.A.	6.207 (1.837, 20.981) 0.0008	
>= 75	34	2 (5.9)	N.A.	37	1 (2.7)	N.A.	2.037 (0.185, 22.477) 0.5529	

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Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2457
FEMALE	68	11 (16.2)	N.A.	65	2 (3.1)	N.A.	5.705 (1.264, 25.740) 0.0104	
MALE	236	20 (8.5)	N.A.	223	9 (4.0)	N.A.	2.126 (0.968, 4.670) 0.0545	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.4560
WHITE	211	8 (3.8)	N.A.	214	1 (0.5)	N.A.	8.133 (1.017, 65.023) 0.0184	
ASIAN	75	23 (30.7)	N.A.	59	10 (16.9)	N.A.	2.005 (0.954, 4.216) 0.0621	
OTHER	17	0	N.E.	12	0	N.E.	N.E. N.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9735
US	19	5 (26.3)	N.A. (2.56, N.A.)	20	0	N.E.	N.E. 0.0150	
ASIA	72	22 (30.6)	N.A.	57	10 (17.5)	N.A.	1.922 (0.910, 4.062) 0.0829	
EUROPE	134	3 (2.2)	N.A.	134	0	N.E.	N.E. 0.0833	
REST OF THE WORLD	79	1 (1.3)	N.A.	77	1 (1.3)	N.A.	0.939 (0.059, 15.019) 0.9647	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PERFORMANCE STATUS								0.6542
0	162	20 (12.3)	N.A.	155	8 (5.2)	N.A.	2.496 (1.099, 5.667) 0.0239	
1	140	11 (7.9)	N.A.	133	3 (2.3)	N.A.	3.527 (0.984, 12.643) 0.0390	
LIVER METASTASIS								0.9126
YES	62	6 (9.7)	N.A.	59	2 (3.4)	N.A.	2.940 (0.593, 14.570) 0.1672	
NO	242	25 (10.3)	N.A.	229	9 (3.9)	N.A.	2.697 (1.259, 5.777) 0.0079	

June 2023 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9887
STAGE III	37	2 (5.4)	N.A.	24	0	N.E.	N.E. 0.2565	
STAGE IV	265	29 (10.9)	N.A.	262	10 (3.8)	N.A.	2.963 (1.444, 6.080) 0.0019	
PRIOR RADIOTHERAPY								0.9878
YES	26	4 (15.4)	N.A.	22	0	N.E.	N.E. 0.0579	
NO	278	27 (9.7)	N.A.	266	11 (4.1)	N.A.	2.401 (1.191, 4.840) 0.0116	

June 2023 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								0.1452
YES	88	13 (14.8)	N.A.	61	1 (1.6)	N.A.	9.721 (1.272, 74.313) 0.0070	
NO	216	18 (8.3)	N.A.	227	10 (4.4)	N.A.	1.916 (0.884, 4.151) 0.0936	
PD-L1 STATUS (IRT)								0.2326
>=1%	111	9 (8.1)	N.A.	101	1 (1.0)	N.A.	8.351 (1.058, 65.920) 0.0158	
<1%/INDETERMINATE	193	22 (11.4)	N.A.	187	10 (5.3)	N.A.	2.202 (1.043, 4.651) 0.0339	

June 2023 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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Table 25.2
Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

SOC: Investigations. PT: White Blood Cell Count Decreased

	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LIVER METASTASIS (IRT)								0.4317
YES	64	6 (9.4)	N.A.	61	1 (1.6)	N.A.	5.865 (0.706, 48.706) 0.0632	
NO	240	25 (10.4)	N.A.	227	10 (4.4)	N.A.	2.426 (1.165, 5.051) 0.0145	

June 2023 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
Program Path: /projects/bms214671/stats/market/ma901_202305/prog/tables
Program Name: rt-ae-tsubsoc-ebr2114.sas 25APR2024:05:57:19

Anhang 4-G-1.4.2.4.3: Subgruppenanalysen für häufige schwerwiegende UE auf SOC/PT-Ebene

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Table 25.3
Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT on Hazard Ratio
All Treated Subjects - Arm C and D

Subgroup	Nivolumab + SOC			SOC			Nivolumab + SOC vs. SOC	
	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NO DATA AVAILABLE FOR THIS REPORT								

June 2023 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
Subjects without events are censored 100 days after last dose of study therapy
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified Cox proportional hazard model. HR is nivolumab + SOC over SOC.
(3) Unstratified log-rank test. (4) Unstratified Cox proportional hazard model with treatment,
subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
MedDRA Version: 26.0; CTC Version 4
Race Other includes all the races other than White, Black, Asian, American Indian, and Not reported.
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