Dossier zur Nutzenbewertung gemäß § 35a SGB V

Nivolumab (OPDIVO®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 W

Anhang 4-G

Neoadjuvante Behandlung des resezierbaren, nicht-kleinzelligen Lungenkarzinoms mit Tumorzell-PD-L1-Expression ≥ 1 % bei Erwachsenen mit hohem Rezidivrisiko

Ergänzende Analysen

Stand: 21.07.2023

4 Modul 4 W– Anhang 4-G - Ergänzende Analysen

Inhaltsverzeichnis Anhang 4-G

Anhang 4-G: Ergänzende Analysen der RCT CA209-816

Anhang 4-G 1: Endpunkte Morbidität: Zusatzanalysen (Zeit bis zur ersten Verschlechterung)

Anhang 4-G 1.1: Zeit bis zur ersten Verschlechterung um 7 mm, 10 mm, 15 mm für Endpunkt EQ-5D-VAS aus CA209-816 (PD-L1-positive Population)

Responderanalyse Zeit bis zur ersten Verschlechterung über den gesamten Beobachtungszeitraum um 7 mm, 10 mm, 15 mm des Endpunktes Gesundheitszustand gemäß EQ-5D-VAS aus CA209-816 (PD-L1-positive Population).

	Nivolumab + Chemotherapie (N = 89)			**Chemotherapie (N = 89)**			**Nivolumab + Chemotherapie vs. Chemotherapie**	
EQ-5D (Response-kriterium)	**N[(1)]**	**Patienten mit Ereignis n (%)**	**Mediane Zeit bis zur Verschlechterung in Monaten (95 %-KI)[(2)]**	**N[(1)]**	**Patienten mit Ereignis n (%)**	**Mediane Zeit bis zur Verschlechterung in Monaten (95 %-KI)[(2)]**	**HR[(3)] (95 %-KI)**	**p-Wert[(3)]**
EQ-5D-VAS (MID = 7)	84	64 (76,2)	8,05 (3,45; 18,83)	86	61 (70,9)	3,68 (2,30; 7,98)	0,676 (0,464; 0,983)	0,0405
EQ-5D-VAS (MID = 10)	84	63 (75,0)	10,58 (4,96; 22,83)	86	59 (68,6)	5,55 (2,50; 11,07)	0,742 (0,510; 1,079)	0,1177
EQ-5D-VAS (15)	84	44 (52,4)	34,43 (11,86; 46,95)	86	44 (51,2)	23,46 (16,36; N.A.)	0,815 (0,531; 1,251)	0,3497

EQ-5D = European Quality of Life Questionnaire 5 Dimensions; HR = Hazard Ratio; IRT = Interaktive Antworttechnologie (Interactive Response Technology); KI = Konfidenzintervall; lt. = Laut; MID = Minimal Important Difference; N.A. = Nicht anwendbar bzw. nicht erreicht; VAS = Visuelle Analogskala; vs. = Versus

(1) Anzahl der randomisierten Patienten mit einem Wert zu Studienbeginn.

(2) Das 2-seitige 95 %-KI wurde über eine Log-Log-Transformation (nach Brookmeyer und Crowley) berechnet.

(3) Cox-Modell stratifiziert nach Krankheitsstadium zu Studienbeginn (IB/II vs. IIIA) und Geschlecht (männlich vs. weiblich) lt. IRT mit Werten zu Studienbeginn als Kovariate.

Anhang 4-G 1.2: Endpunkte Morbidität: Details zur Analyse der Zeit bis zur dauerhaften Verschlechterung

Anhang 4-G 1.2.1: Details zur Analyse der Zeit bis zur dauerhaften Verschlechterung (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 3

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Domains	Arm C: Nivo + Chemo N = 84	Arm B: Chemo (Concurrent) N = 86
EQ-5D-VAS (MID=7)		
NUMBER OF EVENTS (%)	35/ 84 (41.7%)	37/ 86 (43.0%)
PATIENTS WITH A SINGLE DETERIORATION AT THE LAST NON-MISSING PRO ASSESSMENT	7/ 35 (20.0%)	1/ 37 (2.7%)
PATIENTS WITH A SINGLE DETERIORATION AT THE LAST NON-MISSING PRO ASSESSMENT AND NO FURTHER DATA AFTERWARDS DUE TO MISSED VISIT OR INCOMPLETE DATA	1/ 35 (2.9%)	4/ 37 (10.8%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	4/ 35 (11.4%)	5/ 37 (13.5%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS WITH A DETERIORATION AT ALL SUBSEQUENT AVAILABLE ASSESSMENTS	23/ 35 (65.7%)	27/ 37 (73.0%)
NUMBER OF SUBJECTS CENSORED (%)	49/ 84 (58.3%)	49/ 86 (57.0%)
CENSORED AT LAST NON-MISSING PRO ASSESSMENT DATE	49/ 49 (100.0%)	47/ 49 (95.9%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT	29/ 49 (59.2%)	24/ 49 (49.0%)
PATIENTS WITH NO DETERIORATION	20/ 49 (40.8%)	23/ 49 (46.9%)
CENSORED AT RANDOMIZATION DATE	0/ 49	2/ 49 (4.1%)
PATIENTS WITH NO BASELINE ASSESSMENT	0/ 49	0/ 49
PATIENTS WITH NO POST-BASELINE PRO ASSESSMENTS	0/ 49	2/ 49 (4.1%)

Oct 2022 DBL
The subjects with missing baseline assessment will be excluded from this analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tddec-ebr1525-batch1.sas 09MAR2023:20:11:17

Protocol: CA209816 Page 2 of 3

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Domains	Arm C: Nivo + Chemo N = 84	Arm B: Chemo (Concurrent) N = 86
EQ-5D-VAS (MID=10)		
NUMBER OF EVENTS (%)	33/ 84 (39.3%)	36/ 86 (41.9%)
PATIENTS WITH A SINGLE DETERIORATION AT THE LAST NON-MISSING PRO ASSESSMENT	7/ 33 (21.2%)	1/ 36 (2.8%)
PATIENTS WITH A SINGLE DETERIORATION AT THE LAST NON-MISSING PRO ASSESSMENT AND NO FURTHER DATA AFTERWARDS DUE TO MISSED VISIT OR INCOMPLETE DATA	2/ 33 (6.1%)	4/ 36 (11.1%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	4/ 33 (12.1%)	5/ 36 (13.9%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS WITH A DETERIORATION AT ALL SUBSEQUENT AVAILABLE ASSESSMENTS	20/ 33 (60.6%)	26/ 36 (72.2%)
NUMBER OF SUBJECTS CENSORED (%)	51/ 84 (60.7%)	50/ 86 (58.1%)
CENSORED AT LAST NON-MISSING PRO ASSESSMENT DATE	51/ 51 (100.0%)	48/ 50 (96.0%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT	30/ 51 (58.8%)	23/ 50 (46.0%)
PATIENTS WITH NO DETERIORATION	21/ 51 (41.2%)	25/ 50 (50.0%)
CENSORED AT RANDOMIZATION DATE	0/ 51	2/ 50 (4.0%)
PATIENTS WITH NO BASELINE ASSESSMENT	0/ 51	0/ 50
PATIENTS WITH NO POST-BASELINE PRO ASSESSMENTS	0/ 51	2/ 50 (4.0%)

Oct 2022 DBL
The subjects with missing baseline assessment will be excluded from this analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tddec-ebr1525-batch1.sas 09MAR2023:20:11:17

Protocol: CA209816 Page 3 of 3

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Domains	Arm C: Nivo + Chemo N = 84	Arm B: Chemo (Concurrent) N = 86
EQ-5D-VAS (MID=15)		
NUMBER OF EVENTS (%)	24/ 84 (28.6%)	22/ 86 (25.6%)
PATIENTS WITH A SINGLE DETERIORATION AT THE LAST NON-MISSING PRO ASSESSMENT	7/ 24 (29.2%)	1/ 22 (4.5%)
PATIENTS WITH A SINGLE DETERIORATION AT THE LAST NON-MISSING PRO ASSESSMENT AND NO FURTHER DATA AFTERWARDS DUE TO MISSED VISIT OR INCOMPLETE DATA	2/ 24 (8.3%)	4/ 22 (18.2%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	3/ 24 (12.5%)	6/ 22 (27.3%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS WITH A DETERIORATION AT ALL SUBSEQUENT AVAILABLE ASSESSMENTS	12/ 24 (50.0%)	11/ 22 (50.0%)
NUMBER OF SUBJECTS CENSORED (%)	60/ 84 (71.4%)	64/ 86 (74.4%)
CENSORED AT LAST NON-MISSING PRO ASSESSMENT DATE	60/ 60 (100.0%)	62/ 64 (96.9%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT	20/ 60 (33.3%)	22/ 64 (34.4%)
PATIENTS WITH NO DETERIORATION	40/ 60 (66.7%)	40/ 64 (62.5%)
CENSORED AT RANDOMIZATION DATE	0/ 60	2/ 64 (3.1%)
PATIENTS WITH NO BASELINE ASSESSMENT	0/ 60	0/ 64
PATIENTS WITH NO POST-BASELINE PRO ASSESSMENTS	0/ 60	2/ 64 (3.1%)

Oct 2022 DBL
The subjects with missing baseline assessment will be excluded from this analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tddec-ebr1525-batch1.sas 09MAR2023:20:11:17

Anhang 4-G 2: Endpunkte Morbidität: Zusatzanalyse (MMRM)

Anhang 4-G 2.1: Zusatzanalyse mit MMRM für Endpunkt EQ-5D-VAS aus CA209-816 (PD-L1-positive Population)

Zusatzanalyse: Änderung zu Studienbeginn (MMRM) des Endpunktes Gesundheitszustand gemäß EQ-5D-VAS aus CA209-816 (PD-L1-positive Population).

	Nivolumab + Chemotherapie (N = 89)			Chemotherapie (N = 89)			Nivolumab + Chemotherapie vs. Chemotherapie	
EQ-5D	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (95 %-KI)[1]**	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (95 %-KI)[1]**	**Mittlere Differenz (95 %-KI) p-Wert[1]**	**SMD als Hedges‘ g (95 %-KI)**
EQ-5D-VAS[2]	84	85,5 (14,0)	-1,08 (-3,17; 1,02)	83	83,6 (12,7)	-0,96 (-2,97; 1,05)	-0,12 (-2,77; 2,53) 0,9305	-0,01 (-0,32; 0,29)

EQ-5D = European Quality of Life Questionnaire 5 Dimensions; KI = Konfidenzintervall; MMRM = Gemischtes Modell für wiederholte Messungen; MW = Mittelwert; N = Anzahl der ausgewerteten Patienten; SD = Standardabweichung; SMD = standardisierte mittlere Differenz; VAS = visueller Analogskalenwert

(1) MMRM mit Änderung zu Studienbeginn als primäre abhängige Variable, Behandlung, Erhebungszeitpunkt, Behandlung*Erhebungszeitpunktinteraktion und die Randomisierungs-Strata als feste Effekte. Kovariaten des Modells sind Werte zu Studienbeginn. Die Erhebungszeitpunkte flossen als wiederholte Messungen ein, wobei nur Zeitpunkte mit mindestens 10 Patienten in jedem Behandlungsarmn ohne die Nachbeobachtungszeitpunkte berücksichtigt wurden. Die Modelle wurden mittels einer unstrukturierten Kovarianzmatrix berechnet. Im Falle von nicht-konvergierenden Modellen wurden Compound Symmetry bzw. danach Auto-Regressive Covariance als alternative Kovarianzstrukturen verwendet.

(2) Eine positive Änderung zu Studienbeginn bedeutet eine Verbesserung; ein positiver Effektschätzer bedeutet einen Vorteil für Nivolumab + Chemotherapie.

Anhang 4-G 3: Endpunkte Verträglichkeit

Anhang 4-G 3.1: Ergebnisse für Endpunkte Unerwünschte Ereignisse in neoadjuvanter Phase aus CA209-816 – Gruppenvergleiche mittels OR, RR, ARR (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 1

Analysis of Adverse Events on Neoadjuvant Treatment Rates
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events on Neoadjuvant Treatment Rate	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%) (95% CI) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%) (95% CI) (1)	Arm C vs. Concurrent Arm B OR [95%CI] (2)	RR [95%CI] (2) RRR [95%CI] (3)	ARR [95%CI] (2)	P-value (4)
SUBJECTS WITH ANY AES	88	85 (96.6) (90.4, 99.3)	89	88 (98.9) (93.9, 100.0)	0.33 (0.03, 3.26)	0.98 (0.94, 1.02)	-2.2% (-6.5%, 2.1%)	0.3215
SUBJECTS WITH CTCAE GRADES >= 3 AES	88	39 (44.3) (33.7, 55.3)	89	59 (66.3) (55.5, 76.0)	0.38 (0.21, 0.71)	0.66 (0.50, 0.87)	-22.8% (-36.4%, -9.1%)	0.0021
SUBJECTS WITH SAES	88	25 (28.4) (19.3, 39.0)	89	21 (23.6) (15.2, 33.8)	1.28 (0.65, 2.51)	1.20 (0.73, 1.97) 0.84 (0.51, 1.38)	4.6% (-8.2%, 17.5%)	0.4854
SUBJECTS WITH AES LEADING TO DISCONTINUATION OF STUDY TREATMENT*	88	11 (12.5) (6.4, 21.3)	89	12 (13.5) (7.2, 22.4)	0.90 (0.39, 2.12)	0.92 (0.43, 1.94)	-1.2% (-11.0%, 8.6%)	0.8169

ARR=absolute risk reduction; OR=odds ratio; RR=relative risk, RRR=reversed relative risk.
If no subjects with or without events in both groups, then ARR=0.00% [0.00%, 0.00%]. N.E. = Not Estimable.
(1) Confidence interval based on the Clopper and Pearson method.
(2) Estimates of OR, RR, RRR, ARR are based on CMH method of weighting, adjusted by the stratification factors.
(3) RRR including CI is only presented if RR>1. (4) Two-sided p-value from CMH Test for the comparison of OR between treatment groups, adjusting by disease stage (IB/II vs IIIA) and sex (male vs female) per IRT
Continuity correction is used for categories marked with an asterisk.
Includes events reported between first dose and 100 days after last dose of neoadjuvant study therapy.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-aet-ebr1525.sas 21MAR2023:11:59:14

Anhang 4-G 3.2: Ergebnisse für Endpunkte Unerwünschte Ereignisse von besonderem Interesse (UESI) aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Anhang 4-G 3.2.1: Ergebnisse für Endpunkte spezifische immunvermittelte UE (imUE) aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Anhang 4-G 3.2.1.1 Ergebnisse für Endpunkte jegliche spezifische immunvermittelte UE aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Immune-mediated Adverse Events Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 IMAES	88	14 (15.9)	N.A.	89	2 (2.2)	N.A.	7.329 (1.665, 32.264)	0.0020
SUBJECTS WITH PNEUMONITIS IMAES	88	1 (1.1)	N.A.	89	1 (1.1)	N.A.	1.024 (0.064, 16.391)	0.9864
SUBJECTS WITH DIARRHEA/COLITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH HEPATITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH RASH IMAES	88	7 (8.0)	N.A.	89	0	N.E.	N.E.	0.0078
SUBJECTS WITH HYPERSENSITIVITY IMAES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3352
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	88	2 (2.3)	N.A.	89	0	N.E.	N.E.	0.1779

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr1525b1.sas 22MAR2023:17:43:18

Protocol: CA209816 Page 2 of 2

Immune-mediated Adverse Events Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-Mediated Adverse Events (IMAE)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
SUBJECTS WITH HYPOPHYSITIS IMAES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3450
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	88	3 (3.4)	N.A.	89	1 (1.1)	N.A.	2.909 (0.302, 27.983)	0.3325
SUBJECTS WITH HYPOTHYROIDISM IMAES	88	0	N.E.	89	1 (1.1)	N.A.	N.E.	0.3238
SUBJECTS WITH THYROIDITIS IMAES	88	3 (3.4)	N.A.	89	0	N.E.	N.E.	0.0912
SUBJECTS WITH HYPERTHYROIDISM IMAES	88	2 (2.3)	N.A.	89	0	N.E.	N.E.	0.1660
SUBJECTS WITH DIABETES MELLITUS IMAES	88	2 (2.3)	N.A.	89	0	N.E.	N.E.	0.1719

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr1525b1.sas 22MAR2023:17:43:18

Anhang 4-G 3.2.1.2Ergebnisse für Endpunkte schwere spezifische immunvermittelte UE aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Immune-mediated Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 IMAES	88	4 (4.5)	N.A.	89	1 (1.1)	N.A.	3.903 (0.436, 34.939)	0.1889
SUBJECTS WITH PNEUMONITIS IMAES	88	0	N.E.	89	1 (1.1)	N.A.	N.E.	0.3352
SUBJECTS WITH DIARRHEA/COLITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH HEPATITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH RASH IMAES	88	2 (2.3)	N.A.	89	0	N.E.	N.E.	0.1650
SUBJECTS WITH HYPERSENSITIVITY IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	88	2 (2.3)	N.A.	89	0	N.E.	N.E.	0.1779

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr1525b1.sas 22MAR2023:17:43:40

Protocol: CA209816 Page 2 of 2

Immune-mediated Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 HYPOPHYSITIS IMAES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3450
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH HYPOTHYROIDISM IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH THYROIDITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH HYPERTHYROIDISM IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH DIABETES MELLITUS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr1525b1.sas 22MAR2023:17:43:40

Anhang 4-G 3.2.1.3 Ergebnisse für Endpunkte schwerwiegende spezifische immunvermittelte UE aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Serious Immune-mediated Adverse Events Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 IMAES	88	4 (4.5)	N.A.	89	1 (1.1)	N.A.	3.952 (0.441, 35.374)	0.1843
SUBJECTS WITH PNEUMONITIS IMAES	88	1 (1.1)	N.A.	89	1 (1.1)	N.A.	1.024 (0.064, 16.391)	0.9864
SUBJECTS WITH DIARRHEA/COLITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH HEPATITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH RASH IMAES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3173
SUBJECTS WITH HYPERSENSITIVITY IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3367

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr1525b1.sas 22MAR2023:17:44:01

Protocol: CA209816 Page 2 of 2

Serious Immune-mediated Adverse Events Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-Mediated Adverse Events (IMAE)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
SUBJECTS WITH HYPOPHYSITIS IMAES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3450
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH HYPOTHYROIDISM IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH THYROIDITIS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH HYPERTHYROIDISM IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH DIABETES MELLITUS IMAES	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr1525b1.sas 22MAR2023:17:44:01

Anhang 4-G 3.2.2: Ergebnisse für Endpunkte spezifische UE (select UE) aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Anhang 4-G 3.2.2.1Ergebnisse für Endpunkte jegliche spezifische UE aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Select Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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	88	49 (55.7)	2.45 (0.53, N.A.)	89	44 (49.4)	5.19 (1.68, N.A.)	1.285 (0.854, 1.934)	0.2338
SUBJECTS WITH ENDOCRINE AES	88	9 (10.2)	N.A.	89	1 (1.1)	N.A.	8.841 (1.120, 69.798)	0.0124
SUBJECTS WITH GASTROINTESTINAL AES	88	10 (11.4)	N.A.	89	13 (14.6)	N.A.	0.762 (0.334, 1.739)	0.5179
SUBJECTS WITH HEPATIC AES	88	10 (11.4)	N.A.	89	14 (15.7)	N.A.	0.717 (0.318, 1.617)	0.4200
SUBJECTS WITH PULMONARY AES	88	2 (2.3)	N.A.	89	1 (1.1)	N.A.	2.033 (0.184, 22.427)	0.5543
SUBJECTS WITH RENAL AES	88	10 (11.4)	N.A.	89	11 (12.4)	N.A.	0.898 (0.381, 2.118)	0.8057
SUBJECTS WITH SKIN AES	88	26 (29.5)	N.A.	89	13 (14.6)	N.A.	2.250 (1.155, 4.383)	0.0147

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahrt-ebr1525b1.sas 22MAR2023:17:47:45

Protocol: CA209816 Page 2 of 2

Select Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events (SLAE)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	88	7 (8.0)	N.A.	89	4 (4.5)	N.A.	1.830 (0.535, 6.259)	0.3286

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahrt-ebr1525b1.sas 22MAR2023:17:47:45

Anhang 4-G 3.2.2.2Ergebnisse für Endpunkte schwere spezifische UE aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 1

Select Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events (SLAE)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
SUBJECTS WITH ANY SELECT AES	88	9 (10.2)	N.A.	89	5 (5.6)	N.A.	1.822 (0.611, 5.437)	0.2750
SUBJECTS WITH ENDOCRINE AES	88	2 (2.3)	N.A.	89	0	N.E.	N.E.	0.1779
SUBJECTS WITH GASTROINTESTINAL AES	88	1 (1.1)	N.A.	89	1 (1.1)	N.A.	1.013 (0.063, 16.197)	0.9927
SUBJECTS WITH HEPATIC AES	88	1 (1.1)	N.A.	89	2 (2.2)	N.A.	0.496 (0.045, 5.467)	0.5586
SUBJECTS WITH PULMONARY AES	88	0	N.E.	89	1 (1.1)	N.A.	N.E.	0.3352
SUBJECTS WITH RENAL AES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3352
SUBJECTS WITH SKIN AES	88	3 (3.4)	N.A.	89	0	N.E.	N.E.	0.0857
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	88	3 (3.4)	N.A.	89	1 (1.1)	N.A.	2.889 (0.301, 27.780)	0.3358

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahrt-ebr1525b1.sas 22MAR2023:17:48:01

Anhang 4-G 3.2.2.3 Ergebnisse für Endpunkte schwerwiegende spezifische UE aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 1

Serious Select Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events (SLAE)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
SUBJECTS WITH ANY SELECT AES	88	7 (8.0)	N.A.	89	3 (3.4)	N.A.	2.291 (0.592, 8.861)	0.2164
SUBJECTS WITH ENDOCRINE AES	88	2 (2.3)	N.A.	89	0	N.E.	N.E.	0.1779
SUBJECTS WITH GASTROINTESTINAL AES	88	0	N.E.	89	1 (1.1)	N.A.	N.E.	0.3173
SUBJECTS WITH HEPATIC AES	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH PULMONARY AES	88	1 (1.1)	N.A.	89	1 (1.1)	N.A.	1.024 (0.064, 16.391)	0.9864
SUBJECTS WITH RENAL AES	88	2 (2.3)	N.A.	89	1 (1.1)	N.A.	1.902 (0.172, 20.973)	0.5934
SUBJECTS WITH SKIN AES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3173
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	88	1 (1.1)	N.A.	89	0	N.E.	N.E.	0.3352

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahrt-ebr1525b1.sas 22MAR2023:17:48:17

Anhang 4-G 3.2.3: Ergebnisse für Endpunkte weitere UE von speziellem Interesse (OESI) aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Anhang 4-G 3.2.3.1Ergebnisse für Endpunkte jegliche weitere UE von speziellem Interesse aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Other Events of Special Interest Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 OESIS	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH DEMYELINATION EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYASTHENIC SYNDROME	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOSITIS/ RHABDOMYOLYSIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr1525b1.sas 22MAR2023:17:45:01

Protocol: CA209816 Page 2 of 2

Other Events of Special Interest Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Other Events of Special Interest (OESI)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
SUBJECTS WITH PANCREATITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH UVEITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr1525b1.sas 22MAR2023:17:45:01

Anhang 4-G 3.2.3.2 Ergebnisse für Endpunkte schwere weitere UE von speziellem Interesse aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Other Events of Special Interest Over the Entire Study Period with CTCAE Grade 3-4-5
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 OESIS	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH DEMYELINATION EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYASTHENIC SYNDROME	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOSITIS/ RHABDOMYOLYSIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr1525b1.sas 22MAR2023:17:45:19

Protocol: CA209816 Page 2 of 2

Other Events of Special Interest Over the Entire Study Period with CTCAE Grade 3-4-5
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 PANCREATITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH UVEITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr1525b1.sas 22MAR2023:17:45:19

Anhang 4-G 3.2.3.3 Ergebnisse für Endpunkte schwerwiegende weitere UE von speziellem Interesse aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Serious Other Events of Special Interest Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 OESIS	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH DEMYELINATION EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYASTHENIC SYNDROME	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOSITIS/ RHABDOMYOLYSIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr1525b1.sas 22MAR2023:17:45:36

Protocol: CA209816 Page 2 of 2

Serious Other Events of Special Interest Over the Entire Study Period
Time-Adjusted Analyses
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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 PANCREATITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.
SUBJECTS WITH UVEITIS EVENT	88	0	N.E.	89	0	N.E.	N.E.	N.E.

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr1525b1.sas 22MAR2023:17:45:36

Anhang 4-G 3.3: Ergebnisse für Endpunkte häufige Unerwünschte Ereignisse auf SOC/PT-Ebene aus CA209-816 (PD-L1-positive Population)

Anhang 4-G 3.3.1: Ergebnisse für Endpunkte häufige jegliche UE auf SOC/PT-Ebene aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 5

Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	88	85 (96.6)	0.13 (0.07, 0.23)	89	88 (98.9)	0.10 (0.07, 0.13)	0.832 (0.612, 1.132)	0.2330
GASTROINTESTINAL DISORDERS	88	58 (65.9)	0.67 (0.16, 2.14)	89	62 (69.7)	0.26 (0.16, 0.95)	0.921 (0.641, 1.322)	0.6418
NAUSEA	88	36 (40.9)	N.A. (1.68, N.A.)	89	42 (47.2)	N.A. (0.99, N.A.)	0.916 (0.584, 1.437)	0.6792
CONSTIPATION	88	34 (38.6)	N.A.	89	31 (34.8)	N.A.	1.134 (0.695, 1.850)	0.6002
VOMITING	88	11 (12.5)	N.A.	89	14 (15.7)	N.A.	0.994 (0.444, 2.223)	0.9724
DIARRHOEA	88	10 (11.4)	N.A.	89	12 (13.5)	N.A.	0.828 (0.357, 1.918)	0.6608
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	88	54 (61.4)	2.66 (0.82, 3.68)	89	52 (58.4)	2.66 (0.92, N.A.)	1.064 (0.724, 1.563)	0.7221
MALAISE	88	14 (15.9)	N.A.	89	15 (16.9)	N.A.	0.919 (0.443, 1.905)	0.8263

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:07

Protocol: CA209816 Page 2 of 5

Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	P-value (3)
ASTHENIA	88	12 (13.6)	N.A.	89	8 (9.0)	N.A.	1.563 (0.638, 3.830)	0.3361
FATIGUE	88	12 (13.6)	N.A.	89	14 (15.7)	N.A.	0.845 (0.390, 1.831)	0.6686
PAIN	88	12 (13.6)	N.A.	89	16 (18.0)	N.A.	0.701 (0.331, 1.483)	0.3495
PYREXIA	88	12 (13.6)	N.A.	89	11 (12.4)	N.A.	1.159 (0.510, 2.632)	0.7243
BLOOD AND LYMPHATIC SYSTEM DISORDERS	88	43 (48.9)	N.A. (1.51, N.A.)	89	53 (59.6)	2.53 (1.41, 6.90)	0.726 (0.483, 1.090)	0.1181
ANAEMIA	88	36 (40.9)	N.A. (2.96, N.A.)	89	38 (42.7)	N.A. (3.02, N.A.)	0.960 (0.606, 1.520)	0.8556
NEUTROPENIA	88	9 (10.2)	N.A.	89	20 (22.5)	N.A.	0.397 (0.180, 0.873)	0.0172
LEUKOPENIA	88	8 (9.1)	N.A.	89	10 (11.2)	N.A.	0.765 (0.302, 1.939)	0.5726

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:07

Protocol: CA209816 Page 3 of 5

Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	P-value (3)
INVESTIGATIONS	88	43 (48.9)	N.A. (1.54, N.A.)	89	45 (50.6)	5.39 (1.38, N.A.)	0.907 (0.597, 1.379)	0.6631
NEUTROPHIL COUNT DECREASED	88	15 (17.0)	N.A.	89	23 (25.8)	N.A. (7.10, N.A.)	0.643 (0.334, 1.238)	0.1806
WHITE BLOOD CELL COUNT DECREASED	88	10 (11.4)	N.A.	89	13 (14.6)	N.A.	0.742 (0.325, 1.693)	0.4804
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	88	43 (48.9)	6.24 (3.22, N.A.)	89	47 (52.8)	4.90 (2.53, N.A.)	0.809 (0.532, 1.230)	0.3264
COUGH	88	13 (14.8)	N.A.	89	15 (16.9)	N.A.	0.859 (0.408, 1.807)	0.6847
HICCUPS	88	11 (12.5)	N.A.	89	16 (18.0)	N.A.	0.640 (0.296, 1.380)	0.2526
METABOLISM AND NUTRITION DISORDERS	88	41 (46.6)	N.A. (2.66, N.A.)	89	42 (47.2)	N.A. (1.68, N.A.)	0.931 (0.604, 1.436)	0.7458
DECREASED APPETITE	88	25 (28.4)	N.A.	89	25 (28.1)	N.A.	0.981 (0.562, 1.711)	0.9363

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:07

Protocol: CA209816 Page 4 of 5

Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	P-value (3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	88	35 (39.8)	N.A. (3.02, N.A.)	89	30 (33.7)	N.A.	1.273 (0.781, 2.076)	0.3382
RASH	88	12 (13.6)	N.A.	89	4 (4.5)	N.A.	3.228 (1.040, 10.020)	0.0317
ALOPECIA	88	10 (11.4)	N.A.	89	16 (18.0)	N.A.	0.635 (0.288, 1.401)	0.2455
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	88	28 (31.8)	N.A.	89	22 (24.7)	N.A.	1.325 (0.757, 2.319)	0.3197
PROCEDURAL PAIN	88	10 (11.4)	N.A.	89	4 (4.5)	N.A.	2.602 (0.815, 8.307)	0.0938
INFECTIONS AND INFESTATIONS	88	22 (25.0)	N.A.	89	17 (19.1)	N.A. (8.71, N.A.)	1.428 (0.748, 2.724)	0.2773
PNEUMONIA	88	9 (10.2)	N.A.	89	6 (6.7)	N.A.	1.488 (0.529, 4.184)	0.4483
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	88	22 (25.0)	N.A.	89	23 (25.8)	N.A.	1.020 (0.568, 1.833)	0.9507

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:07

Protocol: CA209816 Page 5 of 5

Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
ARTHRALGIA	88	11 (12.5)	N.A.	89	4 (4.5)	N.A.	2.898 (0.921, 9.117)	0.0563
NERVOUS SYSTEM DISORDERS	88	22 (25.0)	N.A. (7.33, N.A.)	89	22 (24.7)	N.A.	0.948 (0.521, 1.727)	0.8687
VASCULAR DISORDERS	88	14 (15.9)	N.A.	89	13 (14.6)	N.A.	1.114 (0.523, 2.374)	0.7785
PSYCHIATRIC DISORDERS	88	13 (14.8)	N.A.	89	18 (20.2)	N.A.	0.697 (0.341, 1.424)	0.3188
INSOMNIA	88	7 (8.0)	N.A.	89	10 (11.2)	N.A.	0.682 (0.260, 1.793)	0.4351
CARDIAC DISORDERS	88	10 (11.4)	N.A.	89	14 (15.7)	N.A.	0.701 (0.311, 1.579)	0.3882

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:07

Anhang 4-G 3.3.2: Ergebnisse für Endpunkte häufige schwere UE auf SOC/PT-Ebene aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	88	39 (44.3)	N.A. (2.73, N.A.)	89	60 (67.4)	2.00 (1.28, 3.02)	0.581 (0.387, 0.872)	0.0078
INVESTIGATIONS	88	13 (14.8)	N.A.	89	16 (18.0)	N.A.	0.790 (0.380, 1.644)	0.5267
NEUTROPHIL COUNT DECREASED	88	8 (9.1)	N.A.	89	14 (15.7)	N.A. (7.46, N.A.)	0.628 (0.260, 1.520)	0.2972
BLOOD AND LYMPHATIC SYSTEM DISORDERS	88	11 (12.5)	N.A.	89	27 (30.3)	N.A.	0.353 (0.175, 0.713)	0.0024
NEUTROPENIA	88	6 (6.8)	N.A.	89	15 (16.9)	N.A.	0.362 (0.140, 0.934)	0.0281
ANAEMIA	88	3 (3.4)	N.A.	89	9 (10.1)	N.A.	0.303 (0.082, 1.123)	0.0583
LEUKOPENIA	88	1 (1.1)	N.A.	89	5 (5.6)	N.A.	0.191 (0.022, 1.637)	0.0913
INFECTIONS AND INFESTATIONS	88	8 (9.1)	N.A.	89	6 (6.7)	N.A.	1.435 (0.492, 4.183)	0.5058

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:18

Protocol: CA209816 Page 2 of 2

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	88	3 (3.4)	N.A.	89	6 (6.7)	N.A.	0.492 (0.123, 1.973)	0.3069
METABOLISM AND NUTRITION DISORDERS	88	2 (2.3)	N.A.	89	9 (10.1)	N.A.	0.212 (0.046, 0.985)	0.0294

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:18

Anhang 4-G 3.3.3: Ergebnisse für Endpunkte häufige SUE auf SOC/PT-Ebene aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 1

Serious Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI) (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI) (mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) (2)	Arm C vs. Concurrent Arm B P-value (3)
TOTAL SUBJECTS WITH AN EVENT	88	25 (28.4)	N.A.	89	22 (24.7)	N.A.	1.138 (0.641, 2.022)	0.6591
INFECTIONS AND INFESTATIONS	88	7 (8.0)	N.A.	89	6 (6.7)	N.A.	1.271 (0.422, 3.829)	0.6685
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	88	5 (5.7)	N.A.	89	3 (3.4)	N.A.	1.678 (0.400, 7.032)	0.4743
BLOOD AND LYMPHATIC SYSTEM DISORDERS	88	2 (2.3)	N.A.	89	5 (5.6)	N.A.	0.378 (0.073, 1.955)	0.2279

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Stratified Log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr1525b1.sas 22MAR2023:17:49:26

Anhang 4-G 3.3.4: Ergebnisse für Endpunkte zum Therapieabbruch führende UE auf SOC/PT-Ebene aus CA209-816 – Inzidenzen (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 2

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) / Preferred Term (%)	Arm C: Nivo + Chemo N = 88			Arm B: Chemo (Concurrent) N = 89		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	11 (12.5)	8 (9.1)	0	14 (15.7)	6 (6.7)	0
Investigations	4 (4.5)	2 (2.3)	0	4 (4.5)	1 (1.1)	0
Neutrophil count decreased	2 (2.3)	2 (2.3)	0	3 (3.4)	1 (1.1)	0
Blood creatinine increased	1 (1.1)	0	0	1 (1.1)	0	0
Platelet count decreased	1 (1.1)	0	0	0	0	0
Immune system disorders	3 (3.4)	3 (3.4)	0	0	0	0
Anaphylactic reaction	3 (3.4)	3 (3.4)	0	0	0	0
Infections and infestations	2 (2.3)	2 (2.3)	0	2 (2.2)	1 (1.1)	0
Pneumonia	1 (1.1)	1 (1.1)	0	0	0	0
Sepsis	1 (1.1)	1 (1.1)	0	0	0	0
Enterocolitis infectious	0	0	0	1 (1.1)	1 (1.1)	0
Herpes zoster	0	0	0	1 (1.1)	0	0
Musculoskeletal and connective tissue disorders	1 (1.1)	0	0	0	0	0
Muscular weakness	1 (1.1)	0	0	0	0	0
Skin and subcutaneous tissue disorders	1 (1.1)	1 (1.1)	0	0	0	0
Rash	1 (1.1)	1 (1.1)	0	0	0	0

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
MedDRA Version: 25.0; CTC Version: 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltdcatt-ebr1525.sas 22MAR2023:10:05:35

Protocol: CA209816 Page 2 of 2

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

System Organ Class (%) Preferred Term (%)	Arm C: Nivo + Chemo N = 88			Arm B: Chemo (Concurrent) N = 89		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Blood and lymphatic system disorders	0	0	0	5 (5.6)	4 (4.5)	0
Neutropenia	0	0	0	5 (5.6)	4 (4.5)	0
General disorders and administration site conditions	0	0	0	1 (1.1)	0	0
Asthenia	0	0	0	1 (1.1)	0	0
Metabolism and nutrition disorders	0	0	0	1 (1.1)	0	0
Decreased appetite	0	0	0	1 (1.1)	0	0
Nervous system disorders	0	0	0	2 (2.2)	0	0
Neuropathy peripheral	0	0	0	1 (1.1)	0	0
Taste disorder	0	0	0	1 (1.1)	0	0
Renal and urinary disorders	0	0	0	1 (1.1)	0	0
Chronic kidney disease	0	0	0	1 (1.1)	0	0

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
MedDRA Version: 25.0; CTC Version: 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltdcatt-ebr1525.sas 22MAR2023:10:05:35

Anhang 4-G 4: Zulassungskonforme Teilpopulation

Anhang 4-G 4.1: Charakteristika

Charakterisierung der Studienpopulationen, Patientenfluss, Behandlungs- und Beobachtungsdauer (zulassungskonforme Teilpopulation)

Protocol: CA209816 Page 1 of 3

Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
AGE (YEARS)			
N	81	86	167
MEAN	64.1	63.6	63.9
MEDIAN	64.0	65.5	64.0
MIN , MAX	47 , 82	41 , 84	41 , 84
Q1 , Q3	58.0 , 70.0	59.0 , 70.0	59.0 , 70.0
SD	7.3	8.7	8.1
AGE CATEGORIZATION 1 (%)			
< 65	44 (54.3)	40 (46.5)	84 (50.3)
>= 65	37 (45.7)	46 (53.5)	83 (49.7)
AGE CATEGORIZATION 2 (%)			
< 65	44 (54.3)	40 (46.5)	84 (50.3)
>= 65 AND < 75	32 (39.5)	42 (48.8)	74 (44.3)
>= 75	5 (6.2)	4 (4.7)	9 (5.4)
AGE CATEGORIZATION 3 (%)			
< 65	44 (54.3)	40 (46.5)	84 (50.3)
>= 65 AND < 75	32 (39.5)	42 (48.8)	74 (44.3)
>= 75 AND < 85	5 (6.2)	4 (4.7)	9 (5.4)
>= 85	0	0	0
SEX (%)			
MALE	62 (76.5)	62 (72.1)	124 (74.3)
FEMALE	19 (23.5)	24 (27.9)	43 (25.7)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1687.sas 18MAY2023:15:28:04

Protocol: CA209816 Page 2 of 3

Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
RACE (%)			
WHITE	35 (43.2)	36 (41.9)	71 (42.5)
BLACK OR AFRICAN AMERICAN	1 (1.2)	1 (1.2)	2 (1.2)
ASIAN	45 (55.6)	49 (57.0)	94 (56.3)
ASIAN INDIAN	1 (1.2)	0	1 (0.6)
CHINESE	25 (30.9)	28 (32.6)	53 (31.7)
JAPANESE	16 (19.8)	20 (23.3)	36 (21.6)
ASIAN OTHER	3 (3.7)	1 (1.2)	4 (2.4)
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
OTHER	0	0	0
ETHNICITY (%)			
HISPANIC OR LATINO	0	1 (1.2)	1 (0.6)
NOT HISPANIC OR LATINO	42 (51.9)	39 (45.3)	81 (48.5)
NOT REPORTED	39 (48.1)	46 (53.5)	85 (50.9)
COUNTRY BY GEOGRAPHIC REGION (%)			
NORTH AMERICA	14 (17.3)	21 (24.4)	35 (21.0)
CANADA	3 (3.7)	6 (7.0)	9 (5.4)
UNITED STATES	11 (13.6)	15 (17.4)	26 (15.6)
EUROPE	18 (22.2)	11 (12.8)	29 (17.4)
FRANCE	5 (6.2)	2 (2.3)	7 (4.2)
GREECE	1 (1.2)	0	1 (0.6)
ITALY	1 (1.2)	2 (2.3)	3 (1.8)
ROMANIA	8 (9.9)	4 (4.7)	12 (7.2)
SPAIN	3 (3.7)	3 (3.5)	6 (3.6)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1687.sas 18MAY2023:15:28:04

Protocol: CA209816 Page 3 of 3

Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
ASIA	45 (55.6)	49 (57.0)	94 (56.3)
CHINA	23 (28.4)	28 (32.6)	51 (30.5)
JAPAN	17 (21.0)	20 (23.3)	37 (22.2)
KOREA	3 (3.7)	1 (1.2)	4 (2.4)
TAIWAN	2 (2.5)	0	2 (1.2)
REST OF THE WORLD	4 (4.9)	5 (5.8)	9 (5.4)
ARGENTINA	3 (3.7)	4 (4.7)	7 (4.2)
BRAZIL	0	0	0
TURKEY	1 (1.2)	1 (1.2)	2 (1.2)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1687.sas 18MAY2023:15:28:04

Protocol: CA209816 Page 1 of 3

Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
DISEASE STAGE AT STUDY ENTRY (CRF)			
STAGE IA	0	0	0
STAGE IB	0	0	0
STAGE IIA	13 (16.0)	19 (22.1)	32 (19.2)
STAGE IIB	12 (14.8)	11 (12.8)	23 (13.8)
STAGE IIIA	56 (69.1)	56 (65.1)	112 (67.1)
STAGE IIIB	0	0	0
STAGE IV	0	0	0
CELL TYPE AT STUDY ENTRY			
SQUAMOUS CELL CARCINOMA	42 (51.9)	47 (54.7)	89 (53.3)
NON-SQUAMOUS CELL CARCINOMA	39 (48.1)	39 (45.3)	78 (46.7)
ADENOCARCINOMA	37 (45.7)	39 (45.3)	76 (45.5)
LARGE CELL CARCINOMA	0	0	0
BRONCHO-ALVEOLAR CARCINOMA	0	0	0
OTHER	2 (2.5)	0	2 (1.2)
TOBACCO USE			
NEVER SMOKER	9 (11.1)	8 (9.3)	17 (10.2)
CURRENT/FORMER	72 (88.9)	77 (89.5)	149 (89.2)
UNKNOWN	0	1 (1.2)	1 (0.6)
ELECTRONIC CIGARRETE USE			
NEVER SMOKER	69 (85.2)	78 (90.7)	147 (88.0)
CURRENT/FORMER	2 (2.5)	3 (3.5)	5 (3.0)
UNKNOWN	10 (12.3)	5 (5.8)	15 (9.0)

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1687.sas 19MAY2023:17:40:19

Protocol: CA209816 Page 2 of 3

Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
BASELINE ECOG PS			
0	59 (72.8)	62 (72.1)	121 (72.5)
1	22 (27.2)	24 (27.9)	46 (27.5)
> 1	0	0	0
BASELINE WEIGHT (KG)			
N	81	86	167
MEAN	69.98	67.23	68.57
MEDIAN	68.50	65.45	66.00
MIN, MAX	40.4 , 126.3	44.6 , 114.6	40.4 , 126.3
SD	15.04	13.30	14.19
TIME FROM CURRENT DIAGNOSIS TO RANDOMIZATION (MONTHS)			
N	81	86	167
MEAN	1.33	1.23	1.28
MEDIAN	0.99	1.12	1.02
MIN, MAX	0.1 , 9.1	0.2 , 3.4	0.1 , 9.1
SD	1.13	0.69	0.93
TIME FROM CURRENT DIAGNOSIS TO RANDOMIZATION (%)			
< 1 MONTHS	42 (51.9)	41 (47.7)	83 (49.7)
1 - < 2 MONTHS	26 (32.1)	34 (39.5)	60 (35.9)
2 - < 3 MONTHS	11 (13.6)	9 (10.5)	20 (12.0)
3 - < 4 MONTHS	1 (1.2)	2 (2.3)	3 (1.8)
4 - < 5 MONTHS	0	0	0
>= 5 MONTHS	1 (1.2)	0	1 (0.6)

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1687.sas 19MAY2023:17:40:19

Protocol: CA209816 Page 3 of 3

Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
PD-L1 (CLINICAL DATABASE)			
1-49%	46 (56.8)	46 (53.5)	92 (55.1)
>= 50%	35 (43.2)	40 (46.5)	75 (44.9)
TUMOR TISSUE TMB			
>=12.3 MUT/MB	18 (22.2)	24 (27.9)	42 (25.1)
< 12.3 MUT/MB	25 (30.9)	22 (25.6)	47 (28.1)
NOT EVALUABLE	4 (4.9)	4 (4.7)	8 (4.8)
NOT REPORTED	34 (42.0)	36 (41.9)	70 (41.9)

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1687.sas 19MAY2023:17:40:19

Protocol: CA209816 Page 1 of 3

Subgroup Factors Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
AGE CATEGORIZATION I			
< 65	44 (54.3)	40 (46.5)	84 (50.3)
>= 65	37 (45.7)	46 (53.5)	83 (49.7)
AGE CATEGORIZATION II			
< 65	44 (54.3)	40 (46.5)	84 (50.3)
>= 65 AND < 75	32 (39.5)	42 (48.8)	74 (44.3)
>= 75	5 (6.2)	4 (4.7)	9 (5.4)
SEX (IRT)			
MALE	62 (76.5)	62 (72.1)	124 (74.3)
FEMALE	19 (23.5)	24 (27.9)	43 (25.7)
SEX (CRF)			
MALE	62 (76.5)	62 (72.1)	124 (74.3)
FEMALE	19 (23.5)	24 (27.9)	43 (25.7)
RACE			
WHITE	35 (43.2)	36 (41.9)	71 (42.5)
BLACK OR AFRICAN AMERICAN	1 (1.2)	1 (1.2)	2 (1.2)
ASIAN	45 (55.6)	49 (57.0)	94 (56.3)
REGION			
NORTH AMERICA	14 (17.3)	21 (24.4)	35 (21.0)
EUROPE	18 (22.2)	11 (12.8)	29 (17.4)
ASIA	45 (55.6)	49 (57.0)	94 (56.3)
REST OF THE WORLD	4 (4.9)	5 (5.8)	9 (5.4)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sumsubr1-ebr1687.sas 16MAY2023:14:03:56

Protocol: CA209816 Page 2 of 3

Subgroup Factors Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
BASELINE ECOG PS			
0	59 (72.8)	62 (72.1)	121 (72.5)
>= 1	22 (27.2)	24 (27.9)	46 (27.5)
TOBACCO USE			
NEVER SMOKED	9 (11.1)	8 (9.3)	17 (10.2)
CURRENT/FORMER	72 (88.9)	77 (89.5)	149 (89.2)
UNKNOWN	0	1 (1.2)	1 (0.6)
DISEASE STAGE AT STUDY ENTRY (IRT)			
STAGE IB/II	29 (35.8)	31 (36.0)	60 (35.9)
STAGE IIIA	52 (64.2)	55 (64.0)	107 (64.1)
CELL TYPE AT STUDY ENTRY			
SQUAMOUS CELL CARCINOMA	42 (51.9)	47 (54.7)	89 (53.3)
NON-SQUAMOUS	39 (48.1)	39 (45.3)	78 (46.7)
PD-L1 STATUS (CLINICAL DATABASE) I			
1-49%	46 (56.8)	46 (53.5)	92 (55.1)
>= 50%	35 (43.2)	40 (46.5)	75 (44.9)
TUMOR TISSUE TMB I			
>= 12.3 MUT/MB	18 (22.2)	24 (27.9)	42 (25.1)
< 12.3 MUT/MB	25 (30.9)	22 (25.6)	47 (28.1)
NOT EVALUABLE/NOT REPORTED	38 (46.9)	40 (46.5)	78 (46.7)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sumsubr1-ebr1687.sas 16MAY2023:14:03:56

Protocol: CA209816 Page 3 of 3

Subgroup Factors Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
TUMOR TISSUE TMB II			
OVERALL EVALUABLE	43 (53.1)	46 (53.5)	89 (53.3)
NOT EVALUABLE/NOT REPORTED	38 (46.9)	40 (46.5)	78 (46.7)
TYPE OF PLATINUM THERAPY I			
CISPLATIN	56 (69.1)	64 (74.4)	120 (71.9)
CARBOPLATIN	19 (23.5)	18 (20.9)	37 (22.2)
SWITCHING FROM CISPLATIN TO CARBOPLATIN	5 (6.2)	4 (4.7)	9 (5.4)
NOT REPORTED	1 (1.2)	0	1 (0.6)
TYPE OF PLATINUM THERAPY II			
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	61 (75.3)	68 (79.1)	129 (77.2)
CARBOPLATIN	19 (23.5)	18 (20.9)	37 (22.2)
NOT REPORTED	1 (1.2)	0	1 (0.6)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B			
AVAILABLE IN ARM C	81 (100.0)	64 (74.4)	145 (86.8)
NOT AVAILABLE IN ARM C	0	22 (25.6)	22 (13.2)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sumsubr1-ebr1687.sas 16MAY2023:14:03:56

Protocol: CA209816 Page 1 of 1

Randomized Subject Status Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

Status (%)	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
TREATED	81 (100.0)	86 (100.0)	167 (100.0)
NOT TREATED	0	0	0

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ds-randr1-ebr1687.sas 15MAY2023:16:02:27

Protocol: CA209816 Page 1 of 1

End of Study Subject Status Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

Status (%)	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
ONGOING STUDY	66 (81.5)	49 (57.0)	115 (68.9)
DISCONTINUED STUDY	15 (18.5)	37 (43.0)	52 (31.1)
REASON FOR DISCONTINUATION OF STUDY			
DEATH	13 (16.0)	29 (33.7)	42 (25.1)
SUBJECT WITHDREW CONSENT	2 (2.5)	6 (7.0)	8 (4.8)
LOST TO FOLLOW-UP	0	2 (2.3)	2 (1.2)
DISCONTINUED STUDY DUE TO COVID-19	0	0	0

Subjects with reported death are included in the death category, even if they were off study before the death.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ds-offs-ebr1687.sas 15MAY2023:16:02:47

Protocol: CA209816 Page 1 of 1

Duration of Any Study Therapy Summary
All Treated Subjects in Concurrently Randomized Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
DURATION OF ANY STUDY THERAPY (WEEKS)			
MEAN (SD)	14.81 (10.26)	17.50 (11.57)	16.20 (11.01)
MEDIAN (MIN - MAX)	12.57 (6.1 - 74.1)	13.79 (0.3 - 66.1)	12.86 (0.3 - 74.1)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ex-durther-rad-t1-ebr1687.sas 17MAY2023:19:27:12

Protocol: CA209816 Page 1 of 1

Duration of Neoadjuvant Systemic Therapy Summary
All Treated Subjects in Concurrently Randomized Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
DURATION OF NEOADJUVANT SYSTEMIC THERAPY (WEEKS)			
MEAN (SD)	6.57 (1.10)	6.14 (1.90)	6.35 (1.58)
MEDIAN (MIN - MAX)	6.43 (0.1 - 8.6)	6.29 (0.1 - 9.1)	6.29 (0.1 - 9.1)
DURATION OF NEOADJUVANT SYSTEMIC THERAPY (DAYS)			
MEAN (SD)	46.0 (7.7)	43.0 (13.3)	44.4 (11.0)
MEDIAN (MIN - MAX)	45.0 (1 - 60)	44.0 (1 - 64)	44.0 (1 - 64)
NUMBER OF CYCLES RECEIVED			
1	1 (1.2)	5 (5.8)	6 (3.6)
2	2 (2.5)	8 (9.3)	10 (6.0)
3	78 (96.3)	73 (84.9)	151 (90.4)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ex-durther-ebr1687p.sas 18MAY2023:16:18:27

Protocol: CA209816 Page 1 of 1

Extent of follow-up Summary
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo N = 81	Arm B: Chemo (Concurrent) N = 86	Total N = 167
TIME BETWEEN RANDOMIZATION DATE AND LAST KNOWN ALIVE DATE (FOR SUBJECTS WHO ARE ALIVE) OR DEATH (WEEKS)			
MEAN	164.01	144.26	153.84
MEDIAN	177.43	165.14	173.71
MIN, MAX	11.6, 250.0	6.1, 234.3	6.1, 250.0
Q1, Q3	154.43, 197.00	86.43, 193.57	117.57, 196.00
STANDARD DEVIATION	56.05	63.28	60.51

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-extfur1-ebr1687.sas 16MAY2023:14:04:25

Anhang 4-G 4.2: Ergebnisse der Hauptanalysen

Gesamtüberleben, EFS, EQ-5D-VAS – Zeit bis zur dauerhaften Verschlechterung über den gesamten Beobachtungszeitraum, Unerwünschte Ereignisse ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE (zulassungskonforme Teilpopulation)

Protocol: CA209816 Page 1 of 1

Overall Survival
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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)
81	13 (16.0)	N.A.	86	29 (33.7)	N.A.	0.433 (0.225, 0.833)	0.0098

Oct 2022 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate
(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. Hazard Ratio (Arm C vs Conc. Arm B)
(3) Unstratified Log-rank test
N.A: Not Available
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-osr1-ebr1687.sas 16MAY2023:15:10:24

Protocol: CA209816 Page 1 of 1

Event Free Survival per BICR, AMNOG Definition
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
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)
81	34 (42.0)	N.A. (20.01, N.A.)	86	56 (65.1)	9.56 (4.80, 16.95)	0.512 (0.334, 0.785)	0.0018

Oct 2022 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate
(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. Hazard Ratio (Arm C vs Conc. Arm B)
(3) Unstratified Log-rank test
N.A: Not Available
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-osr1-ebr1687.sas 16MAY2023:15:10:32

Protocol: CA209816 Page 1 of 1

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration
All Randomized Subjects in Concurrent Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

Domains	Arm C: Nivo + Chemo (N = 81)			Arm B: Chemo (Concurrent) (N = 86)			Arm C vs. Concurrent Arm B	
	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 (2)
EQ-5D-VAS (MID=7)	77	33 (42.9)	44.88 (34.43, N.A.)	83	35 (42.2)	40.77 (19.02, N.A.)	0.855 (0.530, 1.379)	0.5208
EQ-5D-VAS (MID=10)	77	31 (40.3)	44.88 (34.86, N.A.)	83	34 (41.0)	40.77 (19.02, N.A.)	0.823 (0.505, 1.342)	0.4347
EQ-5D-VAS (MID=15)	77	23 (29.9)	46.23 (41.30, N.A.)	83	20 (24.1)	N.A.	0.977 (0.534, 1.787)	0.9388

Oct 2022 DBL, HR = hazard ratio; KME = Kaplan-Meier estimate
(1) KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
(2) Unstratified Cox PH model with treatment arm and BL PRO score as covariates. HR is Arm C over Conc. Arm B.
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-eq5dr1-ebr1687.sas 17MAY2023:16:11:21

Protocol: CA209816 Page 1 of 1

Adverse Events Over the Entire Study Period: Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With Stage II-IIIA Disease and PD-L1 Expression Level >= 1%

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Adverse Events (AE)	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 AES	81	78 (96.3)	0.10 (0.07, 0.20)	86	85 (98.8)	0.10 (0.07, 0.13)	0.837 (0.614, 1.140)	0.2331
SUBJECTS WITH CTCAE GRADES 1-2 AES	81	77 (95.1)	0.13 (0.07, 0.23)	86	83 (96.5)	0.10 (0.07, 0.13)	0.867 (0.635, 1.184)	0.3535
SUBJECTS WITH CTCAE GRADES >= 3 AES	81	36 (44.4)	N.A. (2.73, N.A.)	86	58 (67.4)	2.15 (1.28, 3.02)	0.589 (0.388, 0.894)	0.0117
SUBJECTS WITH SAES	81	22 (27.2)	N.A.	86	21 (24.4)	N.A.	1.111 (0.611, 2.020)	0.7312
SUBJECTS WITH AES LEADING TO DISCONTINUATION OF STUDY TREATMENT	81	11 (13.6)	N.A.	86	14 (16.3)	N.A. (7.46, N.A.)	0.900 (0.406, 1.994)	0.7942

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B.
(3) Unstratified Log-rank test.
MedDRA Version: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aetahrxt-ebr1687p.sas 22MAY2023:15:40:39

Anhang 4-G 5: Subgruppenanalysen

Anhang 4-G 5.1: Charakteristika für die Subgruppen zur Platinkomponente

Charakterisierung der Studienpopulationen sowie Behandlungs- und Beobachtungsdauer für die Subgruppen Cisplatin (inkl. Wechsel auf Carboplatin) und Carboplatin

Protocol: CA209816 Page 1 of 3

Table 1
Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Cisplatin or Switching from Cisplatin to Carboplatin

	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
AGE (YEARS)			
N	66	70	136
MEAN	63.9	63.3	63.6
MEDIAN	64.0	64.5	64.0
MIN , MAX	47 , 77	41 , 84	41 , 84
Q1 , Q3	58.0 , 69.0	59.0 , 70.0	58.5 , 70.0
SD	7.1	8.8	8.0
AGE CATEGORIZATION 1 (%)			
< 65	35 (53.0)	35 (50.0)	70 (51.5)
>= 65	31 (47.0)	35 (50.0)	66 (48.5)
AGE CATEGORIZATION 2 (%)			
< 65	35 (53.0)	35 (50.0)	70 (51.5)
>= 65 AND < 75	28 (42.4)	32 (45.7)	60 (44.1)
>= 75	3 (4.5)	3 (4.3)	6 (4.4)
AGE CATEGORIZATION 3 (%)			
< 65	35 (53.0)	35 (50.0)	70 (51.5)
>= 65 AND < 75	28 (42.4)	32 (45.7)	60 (44.1)
>= 75 AND < 85	3 (4.5)	3 (4.3)	6 (4.4)
>= 85	0	0	0
SEX (%)			
MALE	48 (72.7)	51 (72.9)	99 (72.8)
FEMALE	18 (27.3)	19 (27.1)	37 (27.2)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1748.sas 07JUN2023:06:54:40

Protocol: CA209816 Page 2 of 3

Table 1
Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Cisplatin or Switching from Cisplatin to Carboplatin

	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
RACE (%)			
WHITE	32 (48.5)	28 (40.0)	60 (44.1)
BLACK OR AFRICAN AMERICAN	0	0	0
ASIAN	34 (51.5)	42 (60.0)	76 (55.9)
ASIAN INDIAN	1 (1.5)	0	1 (0.7)
CHINESE	15 (22.7)	24 (34.3)	39 (28.7)
JAPANESE	15 (22.7)	18 (25.7)	33 (24.3)
ASIAN OTHER	3 (4.5)	0	3 (2.2)
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
OTHER	0	0	0
ETHNICITY (%)			
HISPANIC OR LATINO	0	1 (1.4)	1 (0.7)
NOT HISPANIC OR LATINO	41 (62.1)	31 (44.3)	72 (52.9)
NOT REPORTED	25 (37.9)	38 (54.3)	63 (46.3)
COUNTRY BY GEOGRAPHIC REGION (%)			
NORTH AMERICA	13 (19.7)	13 (18.6)	26 (19.1)
CANADA	3 (4.5)	4 (5.7)	7 (5.1)
UNITED STATES	10 (15.2)	9 (12.9)	19 (14.0)
EUROPE	15 (22.7)	10 (14.3)	25 (18.4)
FRANCE	4 (6.1)	2 (2.9)	6 (4.4)
GREECE	1 (1.5)	0	1 (0.7)
ITALY	1 (1.5)	1 (1.4)	2 (1.5)
ROMANIA	8 (12.1)	4 (5.7)	12 (8.8)
SPAIN	1 (1.5)	3 (4.3)	4 (2.9)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1748.sas 07JUN2023:06:54:40

Protocol: CA209816 Page 3 of 3

Table 1
Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Cisplatin or Switching from Cisplatin to Carboplatin

	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
ASIA	34 (51.5)	42 (60.0)	76 (55.9)
CHINA	13 (19.7)	24 (34.3)	37 (27.2)
JAPAN	16 (24.2)	18 (25.7)	34 (25.0)
KOREA	3 (4.5)	0	3 (2.2)
TAIWAN	2 (3.0)	0	2 (1.5)
REST OF THE WORLD	4 (6.1)	5 (7.1)	9 (6.6)
ARGENTINA	3 (4.5)	4 (5.7)	7 (5.1)
BRAZIL	0	0	0
TURKEY	1 (1.5)	1 (1.4)	2 (1.5)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1748.sas 07JUN2023:06:54:40

Protocol: CA209816 Page 1 of 3

Table 3
Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Cisplatin or Switching from Cisplatin to Carboplatin

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
DISEASE STAGE AT STUDY ENTRY (CRF)			
STAGE IA	0	0	0
STAGE IB	5 (7.6)	1 (1.4)	6 (4.4)
STAGE IIA	10 (15.2)	17 (24.3)	27 (19.9)
STAGE IIB	9 (13.6)	6 (8.6)	15 (11.0)
STAGE IIIA	42 (63.6)	45 (64.3)	87 (64.0)
STAGE IIIB	0	0	0
STAGE IV	0	1 (1.4)	1 (0.7)
CELL TYPE AT STUDY ENTRY			
SQUAMOUS CELL CARCINOMA	30 (45.5)	36 (51.4)	66 (48.5)
NON-SQUAMOUS CELL CARCINOMA	36 (54.5)	34 (48.6)	70 (51.5)
ADENOCARCINOMA	35 (53.0)	34 (48.6)	69 (50.7)
LARGE CELL CARCINOMA	0	0	0
BRONCHO-ALVEOLAR CARCINOMA	0	0	0
OTHER	1 (1.5)	0	1 (0.7)
TOBACCO USE			
NEVER SMOKER	7 (10.6)	7 (10.0)	14 (10.3)
CURRENT/FORMER	59 (89.4)	62 (88.6)	121 (89.0)
UNKNOWN	0	1 (1.4)	1 (0.7)
ELECTRONIC CIGARRETE USE			
NEVER SMOKER	57 (86.4)	63 (90.0)	120 (88.2)
CURRENT/FORMER	3 (4.5)	2 (2.9)	5 (3.7)
UNKNOWN	6 (9.1)	5 (7.1)	11 (8.1)

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1748.sas 07JUN2023:15:46:05

Protocol: CA209816 Page 2 of 3

Table 3
Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Cisplatin or Switching from Cisplatin to Carboplatin

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
BASELINE ECOG PS			
0	50 (75.8)	52 (74.3)	102 (75.0)
1	16 (24.2)	18 (25.7)	34 (25.0)
> 1	0	0	0
BASELINE WEIGHT (KG)			
N	66	70	136
MEAN	70.75	65.75	68.18
MEDIAN	69.00	64.75	66.85
MIN, MAX	40.4 , 111.5	44.6 , 114.6	40.4 , 114.6
SD	13.86	12.69	13.46
TIME FROM CURRENT DIAGNOSIS TO RANDOMIZATION (MONTHS)			
N	66	70	136
MEAN	1.40	1.14	1.27
MEDIAN	1.13	0.97	1.03
MIN, MAX	0.1 , 9.1	0.2 , 2.7	0.1 , 9.1
SD	1.21	0.62	0.96

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1748.sas 07JUN2023:15:46:05

Protocol: CA209816 Page 3 of 3

Table 3
Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Cisplatin or Switching from Cisplatin to Carboplatin

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
TIME FROM CURRENT DIAGNOSIS TO RANDOMIZATION (%)			
< 1 MONTHS	30 (45.5)	37 (52.9)	67 (49.3)
1 - < 2 MONTHS	24 (36.4)	25 (35.7)	49 (36.0)
2 - < 3 MONTHS	10 (15.2)	8 (11.4)	18 (13.2)
3 - < 4 MONTHS	1 (1.5)	0	1 (0.7)
4 - < 5 MONTHS	0	0	0
>= 5 MONTHS	1 (1.5)	0	1 (0.7)
PD-L1 (CLINICAL DATABASE)			
1-49%	38 (57.6)	39 (55.7)	77 (56.6)
>= 50%	28 (42.4)	31 (44.3)	59 (43.4)
TUMOR TISSUE TMB			
>=12.3 MUT/MB	18 (27.3)	19 (27.1)	37 (27.2)
< 12.3 MUT/MB	21 (31.8)	17 (24.3)	38 (27.9)
NOT EVALUABLE	3 (4.5)	3 (4.3)	6 (4.4)
NOT REPORTED	24 (36.4)	31 (44.3)	55 (40.4)

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1748.sas 07JUN2023:15:46:05

Protocol: CA209816 Page 1 of 1

Table 7.1.1
Duration of Any Study Therapy Summary
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%
Type of Platinum Therapy: Cisplatin or Switching from Cisplatin to Carboplatin

	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
DURATION OF ANY STUDY THERAPY (WEEKS)			
MEAN (SD)	16.16 (10.13)	18.71 (10.29)	17.28 (10.27)
MEDIAN (MIN - MAX)	13.00 (6.1 - 66.0)	17.57 (0.3 - 64.1)	13.57 (0.3 - 66.0)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms227017/stats/secpub/sp816/oct2022/prog/tables/rt-ex-T_002-ebr1821.sas 11JUL2023:13:00:15

Protocol: CA209816 Page 1 of 1

Table 1.1.1
Duration of Neoadjuvant Systemic Therapy Summary
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%
Type of Platinum Therapy: Cisplatin or Switching from Cisplatin to Carboplatin

	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
DURATION OF NEOADJUVANT SYSTEMIC THERAPY (WEEKS)			
MEAN (SD)	6.73 (0.95)	6.21 (1.89)	6.46 (1.53)
MEDIAN (MIN - MAX)	6.64 (3.1 - 9.1)	6.29 (0.1 - 9.1)	6.43 (0.1 - 9.1)
DURATION OF NEOADJUVANT SYSTEMIC THERAPY (DAYS)			
MEAN (SD)	47.14 (6.64)	43.44 (13.26)	45.24 (10.71)
MEDIAN (MIN - MAX)	46.50 (22.0 - 64.0)	44.00 (1.0 - 64.0)	45.00 (1.0 - 64.0)
NUMBER OF CYCLES RECEIVED			
1	0	3 (4.3)	3 (2.2)
2	2 (3.0)	5 (7.1)	7 (5.1)
3	64 (97.0)	62 (88.6)	126 (92.6)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms227017/stats/secpub/sp816/oct2022/prog/tables/rt-ex-T_002-ebr1821.sas 11JUL2023:13:00:45

Protocol: CA209816 Page 1 of 1

Table 21.1.1
Extent of follow-up Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
Type of Platinum Therapy: Cisplatin or Switching from Cisplatin to Carboplatin

	Arm C: Nivo + Chemo N = 66	Arm B: Chemo (Concurrent) N = 70	Total N = 136
TIME BETWEEN RANDOMIZATION DATE AND LAST KNOWN ALIVE DATE (FOR SUBJECTS WHO ARE ALIVE) OR DEATH (WEEKS)			
MEAN	171.94	146.41	158.80
MEDIAN	182.93	174.21	180.71
MIN, MAX	11.6, 250.0	6.1, 234.3	6.1, 250.0
Q1, Q3	160.57, 202.86	80.86, 200.43	140.79, 201.57
STANDARD DEVIATION	55.26	67.08	62.72

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms227017/stats/secpub/sp816/oct2022/prog/tables/rt-ef-extfu-ebr1821.sas 06JUL2023:19:19:24

Protocol: CA209816 Page 1 of 3

Table 2
Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Carboplatin

	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
AGE (YEARS)			
N	21	19	40
MEAN	64.8	64.7	64.7
MEDIAN	64.0	67.0	65.5
MIN , MAX	54 , 82	49 , 78	49 , 82
Q1 , Q3	61.0 , 68.0	59.0 , 71.0	59.5 , 70.5
SD	6.9	8.1	7.4
AGE CATEGORIZATION 1 (%)			
< 65	12 (57.1)	7 (36.8)	19 (47.5)
>= 65	9 (42.9)	12 (63.2)	21 (52.5)
AGE CATEGORIZATION 2 (%)			
< 65	12 (57.1)	7 (36.8)	19 (47.5)
>= 65 AND < 75	8 (38.1)	11 (57.9)	19 (47.5)
>= 75	1 (4.8)	1 (5.3)	2 (5.0)
AGE CATEGORIZATION 3 (%)			
< 65	12 (57.1)	7 (36.8)	19 (47.5)
>= 65 AND < 75	8 (38.1)	11 (57.9)	19 (47.5)
>= 75 AND < 85	1 (4.8)	1 (5.3)	2 (5.0)
>= 85	0	0	0
SEX (%)			
MALE	18 (85.7)	14 (73.7)	32 (80.0)
FEMALE	3 (14.3)	5 (26.3)	8 (20.0)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1748.sas 07JUN2023:06:54:55

Protocol: CA209816 Page 2 of 3

Table 2
Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Carboplatin

	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
RACE (%)			
WHITE	4 (19.0)	8 (42.1)	12 (30.0)
BLACK OR AFRICAN AMERICAN	1 (4.8)	1 (5.3)	2 (5.0)
ASIAN	16 (76.2)	10 (52.6)	26 (65.0)
ASIAN INDIAN	0	0	0
CHINESE	13 (61.9)	7 (36.8)	20 (50.0)
JAPANESE	2 (9.5)	2 (10.5)	4 (10.0)
ASIAN OTHER	1 (4.8)	1 (5.3)	2 (5.0)
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
OTHER	0	0	0
ETHNICITY (%)			
HISPANIC OR LATINO	0	0	0
NOT HISPANIC OR LATINO	4 (19.0)	8 (42.1)	12 (30.0)
NOT REPORTED	17 (81.0)	11 (57.9)	28 (70.0)
COUNTRY BY GEOGRAPHIC REGION (%)			
NORTH AMERICA	2 (9.5)	8 (42.1)	10 (25.0)
CANADA	0	2 (10.5)	2 (5.0)
UNITED STATES	2 (9.5)	6 (31.6)	8 (20.0)
EUROPE	3 (14.3)	1 (5.3)	4 (10.0)
FRANCE	1 (4.8)	0	1 (2.5)
GREECE	0	0	0
ITALY	0	1 (5.3)	1 (2.5)
ROMANIA	0	0	0
SPAIN	2 (9.5)	0	2 (5.0)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1748.sas 07JUN2023:06:54:55

Protocol: CA209816 Page 3 of 3

Table 2
Demographic Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Carboplatin

	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
ASIA	16 (76.2)	10 (52.6)	26 (65.0)
CHINA	13 (61.9)	7 (36.8)	20 (50.0)
JAPAN	2 (9.5)	2 (10.5)	4 (10.0)
KOREA	1 (4.8)	1 (5.3)	2 (5.0)
TAIWAN	0	0	0
REST OF THE WORLD	0	0	0
ARGENTINA	0	0	0
BRAZIL	0	0	0
TURKEY	0	0	0

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dm-sumr1-ebr1748.sas 07JUN2023:06:54:55

Protocol: CA209816 Page 1 of 3

Table 4
Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Carboplatin

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
DISEASE STAGE AT STUDY ENTRY (CRF)			
STAGE IA	0	0	0
STAGE IB	2 (9.5)	1 (5.3)	3 (7.5)
STAGE IIA	2 (9.5)	2 (10.5)	4 (10.0)
STAGE IIB	3 (14.3)	5 (26.3)	8 (20.0)
STAGE IIIA	14 (66.7)	11 (57.9)	25 (62.5)
STAGE IIIB	0	0	0
STAGE IV	0	0	0
CELL TYPE AT STUDY ENTRY			
SQUAMOUS CELL CARCINOMA	16 (76.2)	14 (73.7)	30 (75.0)
NON-SQUAMOUS CELL CARCINOMA	5 (23.8)	5 (26.3)	10 (25.0)
ADENOCARCINOMA	4 (19.0)	5 (26.3)	9 (22.5)
LARGE CELL CARCINOMA	0	0	0
BRONCHO-ALVEOLAR CARCINOMA	0	0	0
OTHER	1 (4.8)	0	1 (2.5)
TOBACCO USE			
NEVER SMOKER	2 (9.5)	1 (5.3)	3 (7.5)
CURRENT/FORMER	19 (90.5)	18 (94.7)	37 (92.5)
UNKNOWN	0	0	0
ELECTRONIC CIGARRETE USE			
NEVER SMOKER	17 (81.0)	18 (94.7)	35 (87.5)
CURRENT/FORMER	0	1 (5.3)	1 (2.5)
UNKNOWN	4 (19.0)	0	4 (10.0)

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1748.sas 07JUN2023:15:46:17

Protocol: CA209816 Page 2 of 3

Table 4
Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Carboplatin

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
BASELINE ECOG PS			
0	16 (76.2)	11 (57.9)	27 (67.5)
1	5 (23.8)	8 (42.1)	13 (32.5)
> 1	0	0	0
BASELINE WEIGHT (KG)			
N	21	19	40
MEAN	68.33	72.63	70.37
MEDIAN	64.00	70.00	69.50
MIN, MAX	44.0 , 126.3	47.5 , 101.4	44.0 , 126.3
SD	16.69	13.61	15.27
TIME FROM CURRENT DIAGNOSIS TO RANDOMIZATION (MONTHS)			
N	21	19	40
MEAN	1.00	1.50	1.24
MEDIAN	0.85	1.45	0.97
MIN, MAX	0.5 , 3.0	0.3 , 3.4	0.3 , 3.4
SD	0.58	0.83	0.74

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1748.sas 07JUN2023:15:46:17

Protocol: CA209816 Page 3 of 3

Table 4
Baseline Disease Characteristics Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
and Type of Platinum Therapy Carboplatin

	Number of Subjects (%)		
	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
TIME FROM CURRENT DIAGNOSIS TO RANDOMIZATION (%)			
< 1 MONTHS	15 (71.4)	6 (31.6)	21 (52.5)
1 - < 2 MONTHS	5 (23.8)	10 (52.6)	15 (37.5)
2 - < 3 MONTHS	1 (4.8)	1 (5.3)	2 (5.0)
3 - < 4 MONTHS	0	2 (10.5)	2 (5.0)
4 - < 5 MONTHS	0	0	0
>= 5 MONTHS	0	0	0
PD-L1 (CLINICAL DATABASE)			
1-49%	11 (52.4)	8 (42.1)	19 (47.5)
>= 50%	10 (47.6)	11 (57.9)	21 (52.5)
TUMOR TISSUE TMB			
>=12.3 MUT/MB	2 (9.5)	5 (26.3)	7 (17.5)
< 12.3 MUT/MB	4 (19.0)	5 (26.3)	9 (22.5)
NOT EVALUABLE	1 (4.8)	1 (5.3)	2 (5.0)
NOT REPORTED	14 (66.7)	8 (42.1)	22 (55.0)

Subjects in Arm B randomized in the initial protocol are included in Total.
Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-dx-sum-ebr1748.sas 07JUN2023:15:46:17

Protocol: CA209816 Page 1 of 1

Table 7.2.1
Duration of Any Study Therapy Summary
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%
Type of Platinum Therapy: Carboplatin

	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
DURATION OF ANY STUDY THERAPY (WEEKS)			
MEAN (SD)	12.48 (4.33)	21.39 (10.49)	16.58 (8.96)
MEDIAN (MIN - MAX)	12.29 (6.1 - 21.1)	21.43 (3.3 - 43.9)	13.14 (3.3 - 43.9)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms227017/stats/secpub/sp816/oct2022/prog/tables/rt-ex-T_002-ebr1821.sas 11JUL2023:13:00:00

Protocol: CA209816 Page 1 of 1

Table 1.2.1
Duration of Neoadjuvant Systemic Therapy Summary
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%
Type of Platinum Therapy: Carboplatin

	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
DURATION OF NEOADJUVANT SYSTEMIC THERAPY (WEEKS)			
MEAN (SD)	6.48 (0.40)	5.83 (1.86)	6.17 (1.34)
MEDIAN (MIN - MAX)	6.29 (6.1 - 7.6)	6.14 (0.1 - 8.1)	6.14 (0.1 - 8.1)
DURATION OF NEOADJUVANT SYSTEMIC THERAPY (DAYS)			
MEAN (SD)	45.38 (2.78)	40.79 (13.02)	43.20 (9.36)
MEDIAN (MIN - MAX)	44.00 (43.0 - 53.0)	43.00 (1.0 - 57.0)	43.00 (1.0 - 57.0)
NUMBER OF CYCLES RECEIVED			
1	0	1 (5.3)	1 (2.5)
2	0	2 (10.5)	2 (5.0)
3	21 (100.0)	16 (84.2)	37 (92.5)

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms227017/stats/secpub/sp816/oct2022/prog/tables/rt-ex-T_002-ebr1821.sas 11JUL2023:13:00:29

Protocol: CA209816 Page 1 of 1

Table 21.2.1
Extent of follow-up Summary
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%
Type of Platinum Therapy: Carboplatin

	Arm C: Nivo + Chemo N = 21	Arm B: Chemo (Concurrent) N = 19	Total N = 40
TIME BETWEEN RANDOMIZATION DATE AND LAST KNOWN ALIVE DATE (FOR SUBJECTS WHO ARE ALIVE) OR DEATH (WEEKS)			
MEAN	150.67	128.32	140.06
MEDIAN	172.14	151.14	162.50
MIN, MAX	13.9, 219.3	16.3, 182.0	13.9, 219.3
Q1, Q3	154.29, 179.57	81.86, 164.43	103.57, 175.14
STANDARD DEVIATION	53.82	48.92	52.13

Oct 2022 DBL
Program Source: /opt/zfs001/prd/bms227017/stats/secpub/sp816/oct2022/prog/tables/rt-ef-extfu-ebr1821.sas 06JUL2023:19:19:34

Anhang 4-G 5.2: Subgruppenanalysen zu Endpunkten des Hauptteils aus CA209-816 (PD-L1-positive Population)

Anhang 4-G 5.2.1: Subgruppenanalysen für Endpunkte Mortalität – Gesamtüberleben (OS) aus CA209-816 (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
OVERALL	89	13 (14.6)	N.A.	89	31 (34.8)	N.A. (45.08, N.A.)	0.374 (0.195, 0.714) 0.0019	
AGE CATEGORIZATION I								0.4320
< 65	48	5 (10.4)	N.A.	42	13 (31.0)	N.A.	0.288 (0.102, 0.808) 0.0118	
>= 65	41	8 (19.5)	N.A.	47	18 (38.3)	N.A. (28.75, N.A.)	0.482 (0.209, 1.109) 0.0790	
AGE CATEGORIZATION II								0.6582
< 65	48	5 (10.4)	N.A.	42	13 (31.0)	N.A.	0.288 (0.102, 0.808) 0.0118	
>= 65 AND < 75	36	6 (16.7)	N.A.	43	17 (39.5)	N.A. (28.75, N.A.)	0.386 (0.152, 0.981) 0.0377	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 2 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Patients with event n (%)	Arm C: Nivo + Chemo KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Patients with event n (%)	Arm B: Chemo (Concurrent) KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
SEX (IRT)								0.9635
MALE	67	11 (16.4)	N.A.	65	26 (40.0)	N.A. (28.75, N.A.)	0.368 (0.182, 0.745) 0.0038	
FEMALE	22	2 (9.1)	N.A.	24	5 (20.8)	N.A.	0.376 (0.073, 1.942) 0.2248	
SEX (CRF)								0.9785
MALE	66	11 (16.7)	N.A.	65	26 (40.0)	N.A. (28.75, N.A.)	0.374 (0.185, 0.758) 0.0045	
FEMALE	23	2 (8.7)	N.A.	24	5 (20.8)	N.A.	0.360 (0.070, 1.856) 0.2024	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 3 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
RACE								0.3950
WHITE	38	7 (18.4)	N.A.	36	11 (30.6)	N.A. (45.08, N.A.)	0.550 (0.213, 1.420) 0.2083	
ASIAN	50	6 (12.0)	N.A.	52	19 (36.5)	N.A. (28.75, N.A.)	0.297 (0.119, 0.745) 0.0060	
REGION								0.9341
NORTH AMERICA	16	2 (12.5)	N.A.	21	6 (28.6)	N.A. (26.71, N.A.)	0.456 (0.091, 2.284) 0.3278	
EUROPE	19	4 (21.1)	N.A.	11	5 (45.5)	N.A. (5.29, N.A.)	0.369 (0.099, 1.381) 0.1234	
ASIA	50	6 (12.0)	N.A.	52	19 (36.5)	N.A. (28.75, N.A.)	0.297 (0.119, 0.745) 0.0060	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 4 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Patients with event n (%)	Arm C: Nivo + Chemo KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Patients with event n (%)	Arm B: Chemo (Concurrent) KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
BASELINE ECOG PS								0.3621
0	67	10 (14.9)	N.A.	63	19 (30.2)	N.A.	0.464 (0.215, 0.997) 0.0440	
>= 1	22	3 (13.6)	N.A. (15.84, N.A.)	26	12 (46.2)	N.A. (15.84, N.A.)	0.237 (0.067, 0.843) 0.0156	
TOBACCO USE								0.2603
NEVER SMOKED	9	3 (33.3)	N.A. (17.12, N.A.)	8	3 (37.5)	N.A. (13.40, N.A.)	0.847 (0.171, 4.208) 0.8394	
CURRENT/FORMER	80	10 (12.5)	N.A.	80	28 (35.0)	N.A. (45.08, N.A.)	0.319 (0.155, 0.656) 0.0011	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 5 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.9899
STAGE IB/II	36	5 (13.9)	N.A.	34	11 (32.4)	N.A. (26.71, N.A.)	0.382 (0.132, 1.099) 0.0636	
STAGE IIIA	53	8 (15.1)	N.A.	55	20 (36.4)	N.A. (37.22, N.A.)	0.374 (0.165, 0.850) 0.0146	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.9282
STAGE IB/II	32	4 (12.5)	N.A.	32	9 (28.1)	N.A. (45.08, N.A.)	0.413 (0.127, 1.343) 0.1299	
STAGE IIIA	56	9 (16.1)	N.A.	56	21 (37.5)	N.A. (28.75, N.A.)	0.387 (0.177, 0.846) 0.0136	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 6 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Patients with event n (%)	Arm C: Nivo + Chemo KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Patients with event n (%)	Arm B: Chemo (Concurrent) KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.0857
SQUAMOUS CELL CARCINOMA	47	11 (23.4)	N.A. (28.75, N.A.)	50	19 (38.0)	N.A. (28.75, N.A.)	0.580 (0.276, 1.220) 0.1451	
NON-SQUAMOUS	42	2 (4.8)	N.A.	39	12 (30.8)	N.A.	0.132 (0.030, 0.591) 0.0018	
PD-L1 STATUS (CLINICAL DATABASE) I								0.0331*
1-49%	51	12 (23.5)	N.A. (45.08, N.A.)	47	16 (34.0)	N.A. (45.08, N.A.)	0.647 (0.306, 1.369) 0.2506	
>= 50%	38	1 (2.6)	N.A. (28.75, N.A.)	42	15 (35.7)	N.A. (28.75, N.A.)	0.061 (0.008, 0.459) 0.0002	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 7 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
TUMOR TISSUE TMB I								0.7886
>= 12.3 MUT/MB	20	3 (15.0)	N.A.	24	8 (33.3)	N.A. (20.24, N.A.)	0.369 (0.098, 1.395) 0.1259	
< 12.3 MUT/MB	27	5 (18.5)	N.A.	22	7 (31.8)	N.A. (23.72, N.A.)	0.517 (0.164, 1.631) 0.2522	
NOT EVALUABLE/NOT REPORTED	42	5 (11.9)	N.A.	43	16 (37.2)	N.A. (37.22, N.A.)	0.295 (0.108, 0.807) 0.0114	
TUMOR TISSUE TMB II								0.5656
OVERALL EVALUABLE	47	8 (17.0)	N.A.	46	15 (32.6)	N.A. (26.71, N.A.)	0.442 (0.187, 1.044) 0.0560	
NOT EVALUABLE/NOT REPORTED	42	5 (11.9)	N.A.	43	16 (37.2)	N.A. (37.22, N.A.)	0.295 (0.108, 0.807) 0.0114	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 8 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.7834
CISPLATIN	61	8 (13.1)	N.A.	66	22 (33.3)	N.A. (45.08, N.A.)	0.346 (0.154, 0.779) 0.0072	
CARBOPLATIN	21	4 (19.0)	N.A.	19	8 (42.1)	N.A. (20.93, N.A.)	0.402 (0.120, 1.346) 0.1267	
TYPE OF PLATINUM THERAPY II								0.8406
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	9 (13.6)	N.A.	70	23 (32.9)	N.A.	0.367 (0.170, 0.794) 0.0080	
CARBOPLATIN	21	4 (19.0)	N.A.	19	8 (42.1)	N.A. (20.93, N.A.)	0.402 (0.120, 1.346) 0.1267	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Protocol: CA209816 Page 9 of 9

Overall Survival: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	13 (14.8)	N.A.	65	25 (38.5)	N.A. (37.22, N.A.)	0.339 (0.173, 0.664) 0.0009	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	6 (25.0)	N.A.	N.E. N.A.	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:25

Anhang 4-G 5.2.2: Subgruppenanalysen für Endpunkte Morbidität aus CA209-816 (PD-L1-positive Population)

Subgruppenanalysen für die Endpunkte Ereignisfreies Überleben sowie Gesundheitszustand gemäß EQ-5D-VAS (7 mm, 10 mm, 15 mm) – Zeit bis zur dauerhaften Verschlechterung (PD-L1-positive Population)

Anhang 4-G 5.2.2.1: Subgruppenanalysen für den Endpunkt Ereignisfreies Überleben (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
OVERALL	89	37 (41.6)	N.A. (26.55, N.A.)	89	58 (65.2)	9.05 (4.80, 16.95)	0.499 (0.330, 0.755) 0.0008	
AGE CATEGORIZATION I								0.8030
< 65	48	18 (37.5)	N.A. (15.51, N.A.)	42	27 (64.3)	11.47 (3.61, 21.06)	0.483 (0.266, 0.878) 0.0147	
>= 65	41	19 (46.3)	44.42 (8.28, N.A.)	47	31 (66.0)	6.87 (2.99, 24.94)	0.531 (0.299, 0.942) 0.0279	
AGE CATEGORIZATION II								0.9930
< 65	48	18 (37.5)	N.A. (15.51, N.A.)	42	27 (64.3)	11.47 (3.61, 21.06)	0.483 (0.266, 0.878) 0.0147	
>= 65 AND < 75	36	15 (41.7)	44.42 (19.38, N.A.)	43	28 (65.1)	8.61 (3.91, 24.94)	0.474 (0.252, 0.889) 0.0176	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 2 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Patients with event n (%)	Arm C: Nivo + Chemo KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Patients with event n (%)	Arm B: Chemo (Concurrent) KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
SEX (IRT)								0.8295
MALE	67	29 (43.3)	44.42 (19.38, N.A.)	65	43 (66.2)	9.99 (3.68, 18.17)	0.508 (0.316, 0.814) 0.0042	
FEMALE	22	8 (36.4)	N.A. (5.13, N.A.)	24	15 (62.5)	8.11 (2.92, N.A.)	0.470 (0.199, 1.111) 0.0787	
SEX (CRF)								0.9618
MALE	66	28 (42.4)	44.42 (19.38, N.A.)	65	43 (66.2)	9.99 (3.68, 18.17)	0.492 (0.305, 0.794) 0.0030	
FEMALE	23	9 (39.1)	N.A. (5.13, N.A.)	24	15 (62.5)	8.11 (2.92, N.A.)	0.521 (0.227, 1.192) 0.1165	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 3 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
RACE								0.1935
WHITE	38	22 (57.9)	14.47 (3.15, N.A.)	36	26 (72.2)	4.71 (2.86, 21.06)	0.659 (0.373, 1.163) 0.1460	
ASIAN	50	15 (30.0)	N.A. (44.42, N.A.)	52	31 (59.6)	11.47 (5.26, N.A.)	0.381 (0.205, 0.708) 0.0015	
REGION								0.4919
NORTH AMERICA	16	10 (62.5)	3.37 (2.89, N.A.)	21	16 (76.2)	3.68 (2.60, 24.94)	0.709 (0.321, 1.567) 0.3855	
EUROPE	19	10 (52.6)	15.51 (2.99, N.A.)	11	9 (81.8)	8.18 (1.45, 21.06)	0.520 (0.210, 1.288) 0.1507	
ASIA	50	15 (30.0)	N.A. (44.42, N.A.)	52	31 (59.6)	11.47 (5.26, N.A.)	0.381 (0.205, 0.708) 0.0015	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 4 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
BASELINE ECOG PS								0.5732
0	67	24 (35.8)	N.A. (44.42, N.A.)	63	38 (60.3)	14.75 (6.08, 31.80)	0.459 (0.275, 0.767) 0.0023	
>= 1	22	13 (59.1)	4.60 (2.60, N.A.)	26	20 (76.9)	2.83 (2.23, 10.64)	0.617 (0.307, 1.243) 0.1745	
TOBACCO USE								0.6096
NEVER SMOKED	9	5 (55.6)	44.42 (1.81, N.A.)	8	7 (87.5)	12.50 (1.31, N.A.)	0.471 (0.134, 1.659) 0.2315	
CURRENT/FORMER	80	32 (40.0)	N.A. (26.55, N.A.)	80	51 (63.8)	8.54 (3.68, 16.92)	0.474 (0.305, 0.739) 0.0008	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 5 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.8129
STAGE IB/II	36	13 (36.1)	N.A. (8.48, N.A.)	34	20 (58.8)	11.83 (4.80, N.A.)	0.537 (0.267, 1.081) 0.0762	
STAGE IIIA	53	24 (45.3)	44.42 (15.51, N.A.)	55	38 (69.1)	7.92 (2.99, 16.95)	0.479 (0.287, 0.801) 0.0042	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.2634
STAGE IB/II	32	13 (40.6)	N.A. (4.50, N.A.)	32	17 (53.1)	10.41 (3.91, N.A.)	0.705 (0.342, 1.452) 0.3383	
STAGE IIIA	56	23 (41.1)	N.A. (26.55, N.A.)	56	40 (71.4)	8.30 (3.61, 16.92)	0.412 (0.246, 0.690) 0.0005	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 6 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.6066
SQUAMOUS CELL CARCINOMA	47	22 (46.8)	N.A. (5.95, N.A.)	50	34 (68.0)	8.05 (3.61, 11.83)	0.554 (0.324, 0.948) 0.0288	
NON-SQUAMOUS	42	15 (35.7)	N.A. (44.42, N.A.)	39	24 (61.5)	15.67 (2.99, N.A.)	0.443 (0.232, 0.847) 0.0115	
PD-L1 STATUS (CLINICAL DATABASE) I								0.2984
1-49%	51	24 (47.1)	N.A. (8.28, N.A.)	47	31 (66.0)	9.99 (3.91, 21.06)	0.598 (0.350, 1.019) 0.0556	
>= 50%	38	13 (34.2)	N.A. (44.42, N.A.)	42	27 (64.3)	7.92 (2.92, 24.94)	0.391 (0.201, 0.760) 0.0041	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 7 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
TUMOR TISSUE TMB I								0.5891
>= 12.3 MUT/MB	20	6 (30.0)	N.A. (3.15, N.A.)	24	15 (62.5)	11.83 (3.68, N.A.)	0.394 (0.152, 1.018) 0.0464	
< 12.3 MUT/MB	27	15 (55.6)	26.55 (7.92, N.A.)	22	14 (63.6)	8.18 (2.86, N.A.)	0.644 (0.310, 1.339) 0.2373	
NOT EVALUABLE/NOT REPORTED	42	16 (38.1)	N.A. (13.44, N.A.)	43	29 (67.4)	9.56 (2.92, 21.06)	0.446 (0.242, 0.823) 0.0081	
TUMOR TISSUE TMB II								0.6012
OVERALL EVALUABLE	47	21 (44.7)	44.42 (15.51, N.A.)	46	29 (63.0)	8.54 (3.91, 31.80)	0.551 (0.314, 0.968) 0.0353	
NOT EVALUABLE/NOT REPORTED	42	16 (38.1)	N.A. (13.44, N.A.)	43	29 (67.4)	9.56 (2.92, 21.06)	0.446 (0.242, 0.823) 0.0081	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 8 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Patients with event n (%)	KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Test for interaction p-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.3322
CISPLATIN	61	24 (39.3)	N.A. (20.01, N.A.)	66	42 (63.6)	11.47 (5.16, 21.06)	0.483 (0.292, 0.799) 0.0038	
CARBOPLATIN	21	8 (38.1)	N.A. (5.95, N.A.)	19	15 (78.9)	3.68 (2.46, 10.64)	0.323 (0.136, 0.770) 0.0075	
TYPE OF PLATINUM THERAPY II								0.2278
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	27 (40.9)	N.A. (19.38, N.A.)	70	43 (61.4)	14.75 (5.29, 24.94)	0.544 (0.336, 0.881) 0.0120	
CARBOPLATIN	21	8 (38.1)	N.A. (5.95, N.A.)	19	15 (78.9)	3.68 (2.46, 10.64)	0.323 (0.136, 0.770) 0.0075	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Protocol: CA209816 Page 9 of 9

Event Free Survival per BICR, AMNOG Definition: Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Patients with event n (%)	Arm C: Nivo + Chemo KME [95% CI](mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Patients with event n (%)	Arm B: Chemo (Concurrent) KME [95% CI](mon) (1)	Arm C vs. Concurrent Arm B HR [95% CI] p-value (2)(3)	Arm C vs. Concurrent Arm B Test for interaction p-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	36 (40.9)	N.A. (26.55, N.A.)	65	47 (72.3)	8.54 (3.91, 15.67)	0.424 (0.274, 0.656) <0.0001	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	11 (45.8)	N.A. (2.92, N.A.)	N.E. N.A.	

Oct 2022 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.
(2) Unstratified Cox proportional hazard model.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossubr1-ebr1525.sas 21MAR2023:13:56:45

Anhang 4-G 5.2.2.2: Subgruppenanalysen für den Endpunkt Gesundheitszustand gemäß EQ-5D-VAS (7 mm, 10 mm, 15 mm) – Zeit bis zur dauerhaften Verschlechterung (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
OVERALL	84	35 (41.7)	46.23 (34.86, N.A.)	86	37 (43.0)	40.77 (19.02, N.A.)	0.789 (0.496, 1.255) 0.3170	
AGE CATEGORIZATION I								0.3627
< 65	45	20 (44.4)	44.88 (34.43, N.A.)	42	15 (35.7)	N.A. (34.43, N.A.)	1.021 (0.514, 2.026) 0.9526	
>= 65	39	15 (38.5)	46.23 (24.48, N.A.)	44	22 (50.0)	28.39 (16.59, N.A.)	0.667 (0.344, 1.292) 0.2302	
AGE CATEGORIZATION II								0.2630
< 65	45	20 (44.4)	44.88 (34.43, N.A.)	42	15 (35.7)	N.A. (34.43, N.A.)	1.021 (0.514, 2.026) 0.9526	
>= 65 AND < 75	34	12 (35.3)	N.A. (25.59, N.A.)	41	20 (48.8)	28.39 (16.36, N.A.)	0.590 (0.286, 1.219) 0.1541	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 2 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Arm C vs. Concurrent Arm B Test for Interaction p-value (3) (4)
SEX (IRT)								0.8006
MALE	65	30 (46.2)	44.88 (34.43, N.A.)	65	29 (44.6)	34.60 (16.62, N.A.)	0.746 (0.445, 1.250) 0.2657	
FEMALE	19	5 (26.3)	N.A. (5.55, N.A.)	21	8 (38.1)	N.A. (16.99, N.A.)	0.837 (0.272, 2.576) 0.7568	
SEX (CRF)								0.9574
MALE	64	30 (46.9)	44.88 (26.18, N.A.)	65	29 (44.6)	34.60 (16.62, N.A.)	0.768 (0.459, 1.287) 0.3172	
FEMALE	20	5 (25.0)	N.A. (5.55, N.A.)	21	8 (38.1)	N.A. (16.99, N.A.)	0.737 (0.240, 2.262) 0.5939	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 3 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
RACE								0.1208
WHITE	33	12 (36.4)	N.A. (25.59, N.A.)	33	9 (27.3)	N.A. (16.99, N.A.)	1.310 (0.550, 3.119) 0.5418	
ASIAN	50	23 (46.0)	46.23 (25.69, N.A.)	52	27 (51.9)	34.60 (16.59, N.A.)	0.548 (0.310, 0.970) 0.0391	
REGION								0.8021
NORTH AMERICA	16	5 (31.3)	N.A. (8.02, N.A.)	18	6 (33.3)	N.A. (16.82, N.A.)	0.930 (0.282, 3.069) 0.9048	
EUROPE	14	5 (35.7)	N.A. (2.73, N.A.)	11	4 (36.4)	N.A. (4.80, N.A.)	0.759 (0.202, 2.850) 0.6829	
ASIA	50	23 (46.0)	46.23 (25.69, N.A.)	52	27 (51.9)	34.60 (16.59, N.A.)	0.548 (0.310, 0.970) 0.0391	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 4 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Subjects with event n (%)	Arm C: KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Subjects with event n (%)	Arm B: KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B: HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
BASELINE ECOG PS								0.2116
0	64	27 (42.2)	46.23 (40.28, N.A.)	62	23 (37.1)	N.A. (33.41, N.A.)	0.951 (0.543, 1.664) 0.8591	
>= 1	20	8 (40.0)	N.A. (22.83, N.A.)	24	14 (58.3)	16.99 (6.24, N.A.)	0.479 (0.200, 1.151) 0.0998	
TOBACCO USE								0.5565
NEVER SMOKED	9	6 (66.7)	5.55 (0.79, N.A.)	7	5 (71.4)	16.82 (0.76, N.A.)	0.928 (0.261, 3.302) 0.9083	
CURRENT/FORMER	75	29 (38.7)	46.23 (40.28, N.A.)	78	32 (41.0)	40.77 (19.02, N.A.)	0.718 (0.432, 1.191) 0.1992	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 5 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.5046
STAGE IB/II	35	15 (42.9)	46.23 (18.66, N.A.)	33	18 (54.5)	23.70 (13.90, N.A.)	0.676 (0.339, 1.346) 0.2651	
STAGE IIIA	49	20 (40.8)	44.88 (34.43, N.A.)	53	19 (35.8)	N.A. (34.43, N.A.)	0.913 (0.485, 1.718) 0.7774	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.1879
STAGE IB/II	32	13 (40.6)	46.23 (24.48, N.A.)	31	17 (54.8)	28.39 (13.90, N.A.)	0.554 (0.267, 1.147) 0.1117	
STAGE IIIA	52	22 (42.3)	44.88 (26.18, N.A.)	54	19 (35.2)	N.A. (34.43, N.A.)	1.043 (0.563, 1.930) 0.8935	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 6 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
CELL TYPE AT STUDY ENTRY								0.7621
SQUAMOUS CELL CARCINOMA	45	22 (48.9)	40.41 (22.83, N.A.)	49	24 (49.0)	33.41 (16.59, N.A.)	0.853 (0.478, 1.524) 0.5923	
NON-SQUAMOUS	39	13 (33.3)	46.23 (40.28, N.A.)	37	13 (35.1)	N.A. (16.99, N.A.)	0.746 (0.344, 1.618) 0.4579	
PD-L1 STATUS (CLINICAL DATABASE) I								0.5277
1-49%	47	20 (42.6)	44.88 (16.13, N.A.)	45	19 (42.2)	34.73 (16.59, N.A.)	0.916 (0.488, 1.720) 0.7843	
>= 50%	37	15 (40.5)	46.23 (34.86, N.A.)	41	18 (43.9)	40.77 (16.62, N.A.)	0.641 (0.320, 1.284) 0.2098	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 7 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
TUMOR TISSUE TMB I								0.6327
>= 12.3 MUT/MB	20	10 (50.0)	44.88 (5.55, N.A.)	24	8 (33.3)	N.A. (19.02, N.A.)	1.211 (0.475, 3.090) 0.6882	
< 12.3 MUT/MB	24	6 (25.0)	N.A. (34.86, N.A.)	20	6 (30.0)	N.A. (11.07, N.A.)	0.659 (0.208, 2.087) 0.4783	
NOT EVALUABLE/NOT REPORTED	40	19 (47.5)	40.41 (22.83, N.A.)	42	23 (54.8)	34.43 (13.90, N.A.)	0.731 (0.394, 1.358) 0.3214	
TUMOR TISSUE TMB II								0.9027
OVERALL EVALUABLE	44	16 (36.4)	N.A. (26.18, N.A.)	44	14 (31.8)	N.A. (28.39, N.A.)	0.898 (0.434, 1.858) 0.7709	
NOT EVALUABLE/NOT REPORTED	40	19 (47.5)	40.41 (22.83, N.A.)	42	23 (54.8)	34.43 (13.90, N.A.)	0.731 (0.394, 1.358) 0.3214	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 8 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
TYPE OF PLATINUM THERAPY I								0.7446
CISPLATIN	58	20 (34.5)	46.23 (44.88, N.A.)	63	24 (38.1)	N.A. (33.41, N.A.)	0.780 (0.430, 1.415) 0.4130	
CARBOPLATIN	20	12 (60.0)	34.43 (8.05, N.A.)	19	12 (63.2)	16.99 (7.46, N.A.)	0.668 (0.293, 1.525) 0.3386	
TYPE OF PLATINUM THERAPY II								0.6419
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	63	23 (36.5)	46.23 (44.88, N.A.)	67	25 (37.3)	N.A. (33.41, N.A.)	0.825 (0.467, 1.457) 0.5074	
CARBOPLATIN	20	12 (60.0)	34.43 (8.05, N.A.)	19	12 (63.2)	16.99 (7.46, N.A.)	0.668 (0.293, 1.525) 0.3386	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 9 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=7)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	84	35 (41.7)	46.23 (34.86, N.A.)	62	26 (41.9)	40.77 (16.99, N.A.)	0.804 (0.482, 1.339) 0.4012	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	11 (45.8)	34.43 (8.05, N.A.)	N.E.	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 10 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
OVERALL	84	33 (39.3)	46.23 (40.28, N.A.)	86	36 (41.9)	40.77 (19.02, N.A.)	0.764 (0.475, 1.227) 0.2654	
AGE CATEGORIZATION I								0.4607
< 65	45	19 (42.2)	44.88 (34.43, N.A.)	42	15 (35.7)	N.A. (34.43, N.A.)	0.951 (0.475, 1.902) 0.8864	
>= 65	39	14 (35.9)	46.23 (24.48, N.A.)	44	21 (47.7)	33.41 (16.59, N.A.)	0.662 (0.335, 1.310) 0.2362	
AGE CATEGORIZATION II								0.3316
< 65	45	19 (42.2)	44.88 (34.43, N.A.)	42	15 (35.7)	N.A. (34.43, N.A.)	0.951 (0.475, 1.902) 0.8864	
>= 65 AND < 75	34	11 (32.4)	N.A. (46.23, N.A.)	41	19 (46.3)	33.41 (16.36, N.A.)	0.578 (0.273, 1.226) 0.1533	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 11 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Subjects with event n (%)	Arm C: KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Subjects with event n (%)	Arm B: KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B: HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
SEX (IRT)								0.8581
MALE	65	29 (44.6)	44.88 (34.43, N.A.)	65	28 (43.1)	40.77 (16.62, N.A.)	0.757 (0.447, 1.281) 0.2996	
FEMALE	19	4 (21.1)	N.A. (N.A., N.A.)	21	8 (38.1)	N.A. (16.99, N.A.)	0.636 (0.191, 2.121) 0.4615	
SEX (CRF)								0.6459
MALE	64	29 (45.3)	44.88 (34.43, N.A.)	65	28 (43.1)	40.77 (16.62, N.A.)	0.780 (0.461, 1.319) 0.3541	
FEMALE	20	4 (20.0)	N.A. (N.A., N.A.)	21	8 (38.1)	N.A. (16.99, N.A.)	0.562 (0.169, 1.873) 0.3485	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 12 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Arm C vs. Concurrent Arm B Test for Interaction p-value (3) (4)
RACE								0.3504
WHITE	33	10 (30.3)	N.A. (26.18, N.A.)	33	9 (27.3)	N.A. (16.99, N.A.)	1.019 (0.413, 2.515) 0.9674	
ASIAN	50	23 (46.0)	46.23 (25.69, N.A.)	52	26 (50.0)	34.60 (16.59, N.A.)	0.605 (0.341, 1.074) 0.0861	
REGION								0.5974
NORTH AMERICA	16	5 (31.3)	N.A. (8.02, N.A.)	18	6 (33.3)	N.A. (16.82, N.A.)	0.930 (0.282, 3.069) 0.9048	
EUROPE	14	3 (21.4)	N.A. (18.66, N.A.)	11	4 (36.4)	N.A. (4.80, N.A.)	0.364 (0.081, 1.637) 0.1876	
ASIA	50	23 (46.0)	46.23 (25.69, N.A.)	52	26 (50.0)	34.60 (16.59, N.A.)	0.605 (0.341, 1.074) 0.0861	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 13 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Arm C vs. Concurrent Arm B Test for Interaction p-value (3) (4)
BASELINE ECOG PS								0.1216
0	64	26 (40.6)	46.23 (40.28, N.A.)	62	22 (35.5)	N.A. (34.43, N.A.)	0.969 (0.547, 1.716) 0.9129	
>= 1	20	7 (35.0)	N.A. (24.48, N.A.)	24	14 (58.3)	16.99 (6.24, N.A.)	0.389 (0.156, 0.971) 0.0432	
TOBACCO USE								0.7237
NEVER SMOKED	9	4 (44.4)	18.66 (0.79, N.A.)	7	5 (71.4)	16.82 (0.76, N.A.)	0.454 (0.102, 2.023) 0.3001	
CURRENT/FORMER	75	29 (38.7)	46.23 (40.28, N.A.)	78	31 (39.7)	N.A. (19.02, N.A.)	0.757 (0.454, 1.260) 0.2839	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 14 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.6586
STAGE IB/II	35	14 (40.0)	46.23 (24.48, N.A.)	33	17 (51.5)	26.22 (13.90, N.A.)	0.694 (0.341, 1.411) 0.3129	
STAGE IIIA	49	19 (38.8)	44.88 (34.43, N.A.)	53	19 (35.8)	N.A. (34.43, N.A.)	0.849 (0.447, 1.611) 0.6155	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.2720
STAGE IB/II	32	12 (37.5)	46.23 (24.48, N.A.)	31	16 (51.6)	33.41 (13.90, N.A.)	0.570 (0.268, 1.211) 0.1438	
STAGE IIIA	52	21 (40.4)	44.88 (34.43, N.A.)	54	19 (35.2)	N.A. (34.43, N.A.)	0.976 (0.523, 1.818) 0.9379	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 15 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
CELL TYPE AT STUDY ENTRY								0.6084
SQUAMOUS CELL CARCINOMA	45	21 (46.7)	44.88 (24.48, N.A.)	49	23 (46.9)	34.43 (16.59, N.A.)	0.865 (0.478, 1.565) 0.6312	
NON-SQUAMOUS	39	12 (30.8)	46.23 (40.28, N.A.)	37	13 (35.1)	N.A. (16.99, N.A.)	0.679 (0.308, 1.495) 0.3360	
PD-L1 STATUS (CLINICAL DATABASE) I								0.7968
1-49%	47	18 (38.3)	44.88 (26.18, N.A.)	45	19 (42.2)	34.73 (16.59, N.A.)	0.815 (0.427, 1.556) 0.5356	
>= 50%	37	15 (40.5)	46.23 (34.86, N.A.)	41	17 (41.5)	40.77 (16.62, N.A.)	0.694 (0.344, 1.399) 0.3066	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 16 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
TUMOR TISSUE TMB I								0.7665
>= 12.3 MUT/MB	20	8 (40.0)	44.88 (16.13, N.A.)	24	7 (29.2)	N.A. (19.02, N.A.)	1.054 (0.379, 2.933) 0.9195	
< 12.3 MUT/MB	24	6 (25.0)	N.A. (34.86, N.A.)	20	6 (30.0)	N.A. (11.07, N.A.)	0.658 (0.208, 2.082) 0.4762	
NOT EVALUABLE/NOT REPORTED	40	19 (47.5)	40.41 (22.83, N.A.)	42	23 (54.8)	34.43 (13.90, N.A.)	0.749 (0.404, 1.389) 0.3592	
TUMOR TISSUE TMB II								0.9524
OVERALL EVALUABLE	44	14 (31.8)	N.A. (34.86, N.A.)	44	13 (29.5)	N.A. (33.41, N.A.)	0.824 (0.383, 1.773) 0.6209	
NOT EVALUABLE/NOT REPORTED	40	19 (47.5)	40.41 (22.83, N.A.)	42	23 (54.8)	34.43 (13.90, N.A.)	0.749 (0.404, 1.389) 0.3592	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 17 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
TYPE OF PLATINUM THERAPY I								0.9572
CISPLATIN	58	18 (31.0)	46.23 (44.88, N.A.)	63	24 (38.1)	N.A. (33.41, N.A.)	0.686 (0.371, 1.266) 0.2281	
CARBOPLATIN	20	12 (60.0)	34.43 (8.05, N.A.)	19	12 (63.2)	16.99 (9.53, N.A.)	0.673 (0.295, 1.533) 0.3455	
TYPE OF PLATINUM THERAPY II								0.7385
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	63	21 (33.3)	46.23 (44.88, N.A.)	67	24 (35.8)	N.A. (34.43, N.A.)	0.781 (0.434, 1.405) 0.4091	
CARBOPLATIN	20	12 (60.0)	34.43 (8.05, N.A.)	19	12 (63.2)	16.99 (9.53, N.A.)	0.673 (0.295, 1.533) 0.3455	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 18 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=10)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Arm C vs. Concurrent Arm B Test for Interaction p-value (3) (4)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	84	33 (39.3)	46.23 (40.28, N.A.)	62	26 (41.9)	40.77 (16.99, N.A.)	0.748 (0.446, 1.254) 0.2704	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	10 (41.7)	N.A. (10.71, N.A.)	N.E.	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 19 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
OVERALL	84	24 (28.6)	46.23 (41.30, N.A.)	86	22 (25.6)	N.A. (N.A., N.A.)	0.840 (0.469, 1.505) 0.5579	
AGE CATEGORIZATION I								0.5051
< 65	45	15 (33.3)	44.35 (40.41, N.A.)	42	9 (21.4)	N.A. (N.A., N.A.)	1.081 (0.462, 2.530) 0.8577	
>= 65	39	9 (23.1)	46.23 (41.30, N.A.)	44	13 (29.5)	N.A. (33.38, N.A.)	0.675 (0.282, 1.617) 0.3776	
AGE CATEGORIZATION II								0.3478
< 65	45	15 (33.3)	44.35 (40.41, N.A.)	42	9 (21.4)	N.A. (N.A., N.A.)	1.081 (0.462, 2.530) 0.8577	
>= 65 AND < 75	34	7 (20.6)	N.A. (41.30, N.A.)	41	12 (29.3)	N.A. (33.38, N.A.)	0.551 (0.212, 1.433) 0.2217	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 20 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
SEX (IRT)								0.3810
MALE	65	20 (30.8)	46.23 (41.30, N.A.)	65	18 (27.7)	N.A. (37.16, N.A.)	0.719 (0.377, 1.370) 0.3158	
FEMALE	19	4 (21.1)	N.A. (14.32, N.A.)	21	4 (19.0)	N.A. (N.A., N.A.)	1.402 (0.347, 5.657) 0.6350	
SEX (CRF)								0.5568
MALE	64	20 (31.3)	46.23 (41.30, N.A.)	65	18 (27.7)	N.A. (37.16, N.A.)	0.742 (0.390, 1.412) 0.3632	
FEMALE	20	4 (20.0)	N.A. (N.A., N.A.)	21	4 (19.0)	N.A. (N.A., N.A.)	1.254 (0.312, 5.043) 0.7504	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 21 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
RACE								0.6796
WHITE	33	5 (15.2)	N.A. (39.16, N.A.)	33	5 (15.2)	N.A. (37.16, N.A.)	0.850 (0.243, 2.968) 0.7990	
ASIAN	50	19 (38.0)	46.23 (41.30, N.A.)	52	17 (32.7)	N.A. (28.75, N.A.)	0.720 (0.368, 1.407) 0.3363	
REGION								0.7418
NORTH AMERICA	16	1 (6.3)	N.A. (N.A., N.A.)	18	2 (11.1)	N.A. (33.38, N.A.)	0.570 (0.050, 6.445) 0.6500	
EUROPE	14	2 (14.3)	N.A. (39.16, N.A.)	11	3 (27.3)	N.A. (8.02, N.A.)	0.273 (0.038, 1.966) 0.1972	
ASIA	50	19 (38.0)	46.23 (41.30, N.A.)	52	17 (32.7)	N.A. (28.75, N.A.)	0.720 (0.368, 1.407) 0.3363	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 22 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
BASELINE ECOG PS								0.2193
0	64	19 (29.7)	46.23 (41.30, N.A.)	62	13 (21.0)	N.A. (N.A., N.A.)	1.102 (0.539, 2.252) 0.7902	
>= 1	20	5 (25.0)	N.A. (36.34, N.A.)	24	9 (37.5)	34.60 (17.22, N.A.)	0.411 (0.136, 1.242) 0.1151	
TOBACCO USE								0.3056
NEVER SMOKED	9	4 (44.4)	39.16 (0.79, N.A.)	7	2 (28.6)	N.A. (9.53, N.A.)	1.480 (0.236, 9.302) 0.6759	
CURRENT/FORMER	75	20 (26.7)	N.A. (44.06, N.A.)	78	20 (25.6)	N.A. (N.A., N.A.)	0.720 (0.385, 1.346) 0.3035	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 23 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.8863
STAGE IB/II	35	12 (34.3)	46.23 (36.34, N.A.)	33	10 (30.3)	N.A. (24.94, N.A.)	0.833 (0.358, 1.937) 0.6712	
STAGE IIIA	49	12 (24.5)	N.A. (41.30, N.A.)	53	12 (22.6)	N.A. (N.A., N.A.)	0.794 (0.353, 1.788) 0.5779	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.6803
STAGE IB/II	32	10 (31.3)	46.23 (39.16, N.A.)	31	9 (29.0)	N.A. (24.94, N.A.)	0.713 (0.286, 1.775) 0.4670	
STAGE IIIA	52	14 (26.9)	N.A. (41.30, N.A.)	54	12 (22.2)	N.A. (N.A., N.A.)	0.958 (0.439, 2.089) 0.9141	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 24 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
CELL TYPE AT STUDY ENTRY								0.9931
SQUAMOUS CELL CARCINOMA	45	17 (37.8)	41.30 (36.34, N.A.)	49	17 (34.7)	N.A. (22.18, N.A.)	0.872 (0.444, 1.713) 0.6906	
NON-SQUAMOUS	39	7 (17.9)	N.A. (44.06, N.A.)	37	5 (13.5)	N.A. (N.A., N.A.)	0.882 (0.274, 2.835) 0.8333	
PD-L1 STATUS (CLINICAL DATABASE) I								0.8763
1-49%	47	14 (29.8)	N.A. (36.34, N.A.)	45	13 (28.9)	N.A. (33.38, N.A.)	0.874 (0.410, 1.865) 0.7278	
>= 50%	37	10 (27.0)	46.23 (44.06, N.A.)	41	9 (22.0)	N.A. (N.A., N.A.)	0.756 (0.300, 1.903) 0.5527	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 25 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
TUMOR TISSUE TMB I								0.8051
>= 12.3 MUT/MB	20	4 (20.0)	N.A. (36.34, N.A.)	24	3 (12.5)	N.A. (N.A., N.A.)	1.147 (0.242, 5.437) 0.8626	
< 12.3 MUT/MB	24	4 (16.7)	N.A. (40.57, N.A.)	20	4 (20.0)	N.A. (19.55, N.A.)	0.615 (0.151, 2.499) 0.4968	
NOT EVALUABLE/NOT REPORTED	40	16 (40.0)	44.06 (40.41, N.A.)	42	15 (35.7)	N.A. (33.38, N.A.)	0.827 (0.400, 1.710) 0.6080	
TUMOR TISSUE TMB II								0.7245
OVERALL EVALUABLE	44	8 (18.2)	N.A. (40.57, N.A.)	44	7 (15.9)	N.A. (N.A., N.A.)	0.801 (0.285, 2.247) 0.6728	
NOT EVALUABLE/NOT REPORTED	40	16 (40.0)	44.06 (40.41, N.A.)	42	15 (35.7)	N.A. (33.38, N.A.)	0.827 (0.400, 1.710) 0.6080	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 26 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with event n (%)	KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Test for Interaction p-value (3) (4)
TYPE OF PLATINUM THERAPY I								0.4923
CISPLATIN	58	11 (19.0)	N.A. (44.35, N.A.)	63	15 (23.8)	N.A. (N.A., N.A.)	0.602 (0.275, 1.320) 0.2051	
CARBOPLATIN	20	10 (50.0)	40.41 (14.32, N.A.)	19	7 (36.8)	34.60 (19.02, N.A.)	0.830 (0.301, 2.286) 0.7185	
TYPE OF PLATINUM THERAPY II								0.7497
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	63	14 (22.2)	N.A. (44.35, N.A.)	67	15 (22.4)	N.A. (N.A., N.A.)	0.749 (0.360, 1.561) 0.4408	
CARBOPLATIN	20	10 (50.0)	40.41 (14.32, N.A.)	19	7 (36.8)	34.60 (19.02, N.A.)	0.830 (0.301, 2.286) 0.7185	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Protocol: CA209816 Page 27 of 27

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects in Concurrent Arms B and C
With PD-L1 Expression Level >= 1%

EQ-5D-VAS (MID=15)

Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with event n (%)	Arm C: Nivo + Chemo KME [95%CI] (mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with event n (%)	Arm B: Chemo (Concurrent) KME [95%CI] (mon) (1)	Arm C vs. Concurrent Arm B HR [95%CI] p-value (2)	Arm C vs. Concurrent Arm B Test for Interaction p-value (3) (4)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	84	24 (28.6)	46.23 (41.30, N.A.)	62	16 (25.8)	N.A. (37.16, N.A.)	0.797 (0.421, 1.507) 0.4854	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	6 (25.0)	N.A. (22.18, N.A.)	N.E.	

Oct 2022 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.
(2) Unstratified Cox proportional hazard (PH) model with treatment arm and baseline PRO score as covariates.
HR is Arm C over Conc. Arm B; p-value for treatment main effect.
(3) Unstratified Cox PH model with baseline PRO score, treatment, subgroup and treatment*subgroup.
(4) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsub-ebr1525.sas 21MAR2023:18:08:36

Anhang 4-G 5.2.3: Subgruppenanalysen für Endpunkte Verträglichkeit aus CA209-816 (PD-L1-positive Population)

Subgruppenanalysen für die Endpunkte unerwünschte Ereignisse ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE im gesamten Beobachtungszeitraum: jegliche UE, schwere UE, schwerwiegende UE und zum Therapieabbruch führende UE (PD-L1-positive Population).

Anhang 4-G 5.2.3.1: Subgruppenanalysen für den Endpunkt jegliche UE ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	85 (96.6)	0.13 (0.07, 0.23)	89	88 (98.9)	0.10 (0.07, 0.13)	0.827 (0.612, 1.116) 0.1920	
AGE CATEGORIZATION I								0.5887
< 65	47	45 (95.7)	0.13 (0.07, 0.30)	42	42 (100.0)	0.10 (0.07, 0.13)	0.762 (0.497, 1.171) 0.1672	
>= 65	41	40 (97.6)	0.10 (0.07, 0.26)	47	46 (97.9)	0.10 (0.07, 0.16)	0.903 (0.589, 1.385) 0.6190	
AGE CATEGORIZATION II								0.4566
< 65	47	45 (95.7)	0.13 (0.07, 0.30)	42	42 (100.0)	0.10 (0.07, 0.13)	0.762 (0.497, 1.171) 0.1672	
>= 65 AND < 75	36	36 (100.0)	0.13 (0.07, 0.26)	43	42 (97.7)	0.10 (0.07, 0.16)	0.967 (0.614, 1.523) 0.8703	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 2 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.7671
MALE	67	64 (95.5)	0.16 (0.07, 0.30)	65	64 (98.5)	0.10 (0.07, 0.20)	0.826 (0.582, 1.170) 0.2762	
FEMALE	21	21 (100.0)	0.07 (0.07, 0.16)	24	24 (100.0)	0.10 (0.03, 0.16)	0.890 (0.486, 1.630) 0.6745	
SEX (CRF)								0.8341
MALE	66	63 (95.5)	0.16 (0.07, 0.26)	65	64 (98.5)	0.10 (0.07, 0.20)	0.847 (0.597, 1.202) 0.3441	
FEMALE	22	22 (100.0)	0.08 (0.07, 0.16)	24	24 (100.0)	0.10 (0.03, 0.16)	0.763 (0.419, 1.390) 0.3567	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 3 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.8366
WHITE	37	34 (91.9)	0.16 (0.07, 0.30)	36	36 (100.0)	0.15 (0.10, 0.20)	0.808 (0.501, 1.302) 0.3437	
ASIAN	50	50 (100.0)	0.10 (0.07, 0.23)	52	51 (98.1)	0.10 (0.07, 0.13)	0.861 (0.580, 1.278) 0.4613	
REGION								0.9563
NORTH AMERICA	16	16 (100.0)	0.07 (0.03, 0.39)	21	21 (100.0)	0.10 (0.07, 0.16)	0.930 (0.472, 1.832) 0.7943	
EUROPE	18	16 (88.9)	0.21 (0.07, 0.46)	11	11 (100.0)	0.16 (0.03, 0.72)	0.833 (0.381, 1.822) 0.6383	
ASIA	50	50 (100.0)	0.10 (0.07, 0.23)	52	51 (98.1)	0.10 (0.07, 0.13)	0.861 (0.580, 1.278) 0.4613	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 4 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.4143
0	66	66 (100.0)	0.10 (0.07, 0.16)	63	62 (98.4)	0.10 (0.07, 0.13)	0.882 (0.621, 1.253) 0.4872	
>= 1	22	19 (86.4)	0.30 (0.07, 0.72)	26	26 (100.0)	0.18 (0.10, 0.36)	0.657 (0.359, 1.203) 0.1587	
TOBACCO USE								0.2459
NEVER SMOKED	9	8 (88.9)	0.10 (0.03, 0.46)	8	8 (100.0)	0.07 (0.03, 0.26)	0.544 (0.194, 1.521) 0.2220	
CURRENT/FORMER	79	77 (97.5)	0.13 (0.07, 0.23)	80	79 (98.8)	0.10 (0.07, 0.13)	0.856 (0.624, 1.174) 0.2980	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 5 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.3173
STAGE IB/II	36	35 (97.2)	0.11 (0.07, 0.26)	34	34 (100.0)	0.07 (0.07, 0.10)	0.679 (0.418, 1.102) 0.1172	
STAGE IIIA	52	50 (96.2)	0.15 (0.07, 0.26)	55	54 (98.2)	0.13 (0.10, 0.20)	0.902 (0.613, 1.329) 0.5474	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.0877
STAGE IB/II	32	30 (93.8)	0.16 (0.07, 0.36)	32	31 (96.9)	0.07 (0.07, 0.10)	0.602 (0.361, 1.004) 0.0539	
STAGE IIIA	56	55 (98.2)	0.10 (0.07, 0.23)	56	56 (100.0)	0.13 (0.10, 0.20)	1.001 (0.689, 1.456) 0.9291	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 6 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.1763
SQUAMOUS CELL CARCINOMA	47	46 (97.9)	0.10 (0.07, 0.26)	50	50 (100.0)	0.11 (0.07, 0.20)	0.994 (0.665, 1.486) 0.9571	
NON-SQUAMOUS	41	39 (95.1)	0.16 (0.07, 0.26)	39	38 (97.4)	0.10 (0.07, 0.13)	0.666 (0.423, 1.049) 0.0617	
PD-L1 STATUS (CLINICAL DATABASE) I								0.2743
1-49%	50	48 (96.0)	0.13 (0.07, 0.23)	47	46 (97.9)	0.13 (0.10, 0.20)	0.953 (0.635, 1.431) 0.7892	
>= 50%	38	37 (97.4)	0.11 (0.07, 0.30)	42	42 (100.0)	0.10 (0.07, 0.13)	0.699 (0.446, 1.095) 0.1033	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 7 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB I								0.8746
>= 12.3 MUT/MB	20	19 (95.0)	0.07 (0.07, 0.20)	24	24 (100.0)	0.10 (0.07, 0.10)	0.978 (0.529, 1.807) 0.8680	
< 12.3 MUT/MB	26	25 (96.2)	0.20 (0.07, 0.30)	22	21 (95.5)	0.11 (0.03, 0.16)	0.766 (0.425, 1.383) 0.3908	
NOT EVALUABLE/NOT REPORTED	42	41 (97.6)	0.16 (0.07, 0.30)	43	43 (100.0)	0.13 (0.07, 0.23)	0.890 (0.579, 1.368) 0.5852	
TUMOR TISSUE TMB II								0.5657
OVERALL EVALUABLE	46	44 (95.7)	0.10 (0.07, 0.23)	46	45 (97.8)	0.10 (0.07, 0.13)	0.783 (0.513, 1.195) 0.2280	
NOT EVALUABLE/NOT REPORTED	42	41 (97.6)	0.16 (0.07, 0.30)	43	43 (100.0)	0.13 (0.07, 0.23)	0.890 (0.579, 1.368) 0.5852	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 8 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.8363
CISPLATIN	61	58 (95.1)	0.10 (0.07, 0.16)	66	66 (100.0)	0.10 (0.07, 0.13)	0.841 (0.589, 1.199) 0.2867	
CARBOPLATIN	21	21 (100.0)	0.36 (0.10, 0.49)	19	18 (94.7)	0.13 (0.07, 0.23)	0.734 (0.387, 1.390) 0.3546	
TYPE OF PLATINUM THERAPY II								0.7856
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	63 (95.5)	0.10 (0.07, 0.16)	70	70 (100.0)	0.10 (0.07, 0.13)	0.856 (0.608, 1.206) 0.3220	
CARBOPLATIN	21	21 (100.0)	0.36 (0.10, 0.49)	19	18 (94.7)	0.13 (0.07, 0.23)	0.734 (0.387, 1.390) 0.3546	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Protocol: CA209816 Page 9 of 9

Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	85 (96.6)	0.13 (0.07, 0.23)	65	64 (98.5)	0.10 (0.07, 0.13)	0.809 (0.583, 1.123) 0.1930	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	24 (100.0)	0.11 (0.03, 0.26)	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:15:55

Anhang 4-G 5.2.3.2: Subgruppenanalysen für den Endpunkt schwere UE ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	39 (44.3)	N.A. (2.73, N.A.)	89	60 (67.4)	2.00 (1.28, 3.02)	0.588 (0.393, 0.881) 0.0092	
AGE CATEGORIZATION I								0.6845
< 65	47	18 (38.3)	N.A. (2.50, N.A.)	42	25 (59.5)	2.86 (1.64, N.A.)	0.646 (0.352, 1.185) 0.1535	
>= 65	41	21 (51.2)	3.61 (0.95, N.A.)	47	35 (74.5)	1.12 (0.72, 2.46)	0.553 (0.321, 0.952) 0.0299	
AGE CATEGORIZATION II								0.5353
< 65	47	18 (38.3)	N.A. (2.50, N.A.)	42	25 (59.5)	2.86 (1.64, N.A.)	0.646 (0.352, 1.185) 0.1535	
>= 65 AND < 75	36	18 (50.0)	N.A. (0.95, N.A.)	43	33 (76.7)	1.12 (0.53, 2.46)	0.499 (0.280, 0.889) 0.0158	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 2 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.4290
MALE	67	34 (50.7)	4.17 (0.95, N.A.)	65	47 (72.3)	1.61 (0.99, 2.66)	0.619 (0.398, 0.964) 0.0320	
FEMALE	21	5 (23.8)	N.A.	24	13 (54.2)	3.58 (1.12, N.A.)	0.396 (0.141, 1.114) 0.0686	
SEX (CRF)								0.3525
MALE	66	34 (51.5)	3.61 (0.95, N.A.)	65	47 (72.3)	1.61 (0.99, 2.66)	0.633 (0.407, 0.986) 0.0409	
FEMALE	22	5 (22.7)	N.A.	24	13 (54.2)	3.58 (1.12, N.A.)	0.374 (0.133, 1.053) 0.0526	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 3 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Arm C vs. Concurrent Arm B Test for Interaction P-value (4)(5)
RACE								0.1979
WHITE	37	12 (32.4)	N.A. (1.02, N.A.)	36	23 (63.9)	2.23 (1.12, N.A.)	0.392 (0.194, 0.791) 0.0070	
ASIAN	50	26 (52.0)	2.61 (0.72, N.A.)	52	36 (69.2)	1.66 (0.69, 3.02)	0.730 (0.441, 1.210) 0.2171	
REGION								0.3376
NORTH AMERICA	16	7 (43.8)	N.A. (1.02, N.A.)	21	14 (66.7)	2.92 (1.41, N.A.)	0.556 (0.223, 1.385) 0.1984	
EUROPE	18	4 (22.2)	N.A.	11	7 (63.6)	1.64 (0.72, N.A.)	0.292 (0.085, 1.001) 0.0383	
ASIA	50	26 (52.0)	2.61 (0.72, N.A.)	52	36 (69.2)	1.66 (0.69, 3.02)	0.730 (0.441, 1.210) 0.2171	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 4 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.0886
0	66	34 (51.5)	2.99 (0.95, N.A.)	63	44 (69.8)	2.00 (1.22, 2.92)	0.712 (0.455, 1.114) 0.1331	
>= 1	22	5 (22.7)	N.A.	26	16 (61.5)	1.97 (0.72, N.A.)	0.274 (0.100, 0.754) 0.0077	
TOBACCO USE								0.1358
NEVER SMOKED	9	3 (33.3)	N.A. (0.49, N.A.)	8	8 (100.0)	1.36 (0.26, 2.53)	0.209 (0.053, 0.818) 0.0137	
CURRENT/FORMER	79	36 (45.6)	N.A. (2.50, N.A.)	80	51 (63.8)	2.38 (1.38, 3.29)	0.663 (0.432, 1.016) 0.0570	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 5 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.8564
STAGE IB/II	36	17 (47.2)	N.A. (0.92, N.A.)	34	25 (73.5)	1.64 (1.08, 3.06)	0.625 (0.337, 1.161) 0.1320	
STAGE IIIA	52	22 (42.3)	N.A. (2.73, N.A.)	55	35 (63.6)	2.50 (0.72, 5.45)	0.574 (0.336, 0.980) 0.0403	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.2747
STAGE IB/II	32	16 (50.0)	3.61 (0.53, N.A.)	32	21 (65.6)	2.55 (1.08, N.A.)	0.800 (0.417, 1.534) 0.4958	
STAGE IIIA	56	23 (41.1)	N.A. (2.99, N.A.)	56	38 (67.9)	1.66 (0.79, 2.92)	0.499 (0.296, 0.839) 0.0076	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 6 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.0172*
SQUAMOUS CELL CARCINOMA	47	28 (59.6)	1.64 (0.72, N.A.)	50	33 (66.0)	1.63 (0.92, 3.02)	0.903 (0.545, 1.495) 0.6906	
NON-SQUAMOUS	41	11 (26.8)	N.A.	39	27 (69.2)	2.53 (1.08, 4.70)	0.299 (0.147, 0.606) 0.0004	
PD-L1 STATUS (CLINICAL DATABASE) I								0.6710
1-49%	50	21 (42.0)	N.A. (2.73, N.A.)	47	32 (68.1)	2.00 (1.22, 3.06)	0.536 (0.309, 0.932) 0.0245	
>= 50%	38	18 (47.4)	N.A. (0.92, N.A.)	42	28 (66.7)	1.95 (0.72, 3.29)	0.657 (0.363, 1.189) 0.1581	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 7 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB I								0.4813
>= 12.3 MUT/MB	20	8 (40.0)	N.A. (0.92, N.A.)	24	18 (75.0)	1.81 (0.30, 3.06)	0.396 (0.172, 0.914) 0.0246	
< 12.3 MUT/MB	26	11 (42.3)	N.A. (0.95, N.A.)	22	12 (54.5)	3.58 (0.72, N.A.)	0.781 (0.344, 1.772) 0.5594	
NOT EVALUABLE/NOT REPORTED	42	20 (47.6)	N.A. (0.92, N.A.)	43	30 (69.8)	1.64 (1.08, 2.92)	0.643 (0.364, 1.136) 0.1245	
TUMOR TISSUE TMB II								0.6878
OVERALL EVALUABLE	46	19 (41.3)	N.A. (1.58, N.A.)	46	30 (65.2)	2.38 (0.79, 5.45)	0.544 (0.306, 0.968) 0.0351	
NOT EVALUABLE/NOT REPORTED	42	20 (47.6)	N.A. (0.92, N.A.)	43	30 (69.8)	1.64 (1.08, 2.92)	0.643 (0.364, 1.136) 0.1245	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 8 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.8329
CISPLATIN	61	24 (39.3)	N.A. (3.61, N.A.)	66	41 (62.1)	2.73 (1.61, 5.45)	0.560 (0.338, 0.928) 0.0223	
CARBOPLATIN	21	11 (52.4)	2.73 (0.39, N.A.)	19	15 (78.9)	0.92 (0.33, 1.61)	0.545 (0.248, 1.196) 0.1217	
TYPE OF PLATINUM THERAPY II								0.8002
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	27 (40.9)	N.A. (3.19, N.A.)	70	45 (64.3)	2.60 (1.61, 3.58)	0.566 (0.351, 0.913) 0.0178	
CARBOPLATIN	21	11 (52.4)	2.73 (0.39, N.A.)	19	15 (78.9)	0.92 (0.33, 1.61)	0.545 (0.248, 1.196) 0.1217	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Protocol: CA209816 Page 9 of 9

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	39 (44.3)	N.A. (2.73, N.A.)	65	43 (66.2)	2.00 (1.12, 3.58)	0.600 (0.388, 0.926) 0.0196	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	17 (70.8)	2.09 (0.72, 3.02)	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:06

Anhang 4-G 5.2.3.3: Subgruppenanalysen für den Endpunkt schwerwiegende UE ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	25 (28.4)	N.A.	89	21 (23.6)	N.A.	1.206 (0.675, 2.155) 0.5247	
AGE CATEGORIZATION I								0.7676
< 65	47	11 (23.4)	N.A.	42	9 (21.4)	N.A.	1.107 (0.459, 2.673) 0.8212	
>= 65	41	14 (34.1)	N.A. (4.73, N.A.)	47	12 (25.5)	N.A.	1.314 (0.607, 2.840) 0.4885	
AGE CATEGORIZATION II								0.8000
< 65	47	11 (23.4)	N.A.	42	9 (21.4)	N.A.	1.107 (0.459, 2.673) 0.8212	
>= 65 AND < 75	36	13 (36.1)	N.A. (3.61, N.A.)	43	12 (27.9)	N.A.	1.279 (0.583, 2.802) 0.5406	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 2 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.9984
MALE	67	20 (29.9)	N.A.	65	16 (24.6)	N.A.	1.196 (0.620, 2.307) 0.5937	
FEMALE	21	5 (23.8)	N.A.	24	5 (20.8)	N.A.	1.214 (0.351, 4.194) 0.7589	
SEX (CRF)								0.9178
MALE	66	20 (30.3)	N.A.	65	16 (24.6)	N.A.	1.217 (0.631, 2.348) 0.5577	
FEMALE	22	5 (22.7)	N.A.	24	5 (20.8)	N.A.	1.150 (0.333, 3.975) 0.8247	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 3 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.5070
WHITE	37	10 (27.0)	N.A.	36	10 (27.8)	N.A.	0.914 (0.380, 2.196) 0.8432	
ASIAN	50	14 (28.0)	N.A.	52	11 (21.2)	N.A.	1.361 (0.618, 2.998) 0.4418	
REGION								0.8073
NORTH AMERICA	16	5 (31.3)	N.A. (3.61, N.A.)	21	7 (33.3)	N.A. (2.69, N.A.)	0.860 (0.273, 2.710) 0.7961	
EUROPE	18	4 (22.2)	N.A.	11	2 (18.2)	N.A. (1.28, N.A.)	1.245 (0.228, 6.801) 0.7997	
ASIA	50	14 (28.0)	N.A.	52	11 (21.2)	N.A.	1.361 (0.618, 2.998) 0.4418	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 4 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.3927
0	66	20 (30.3)	N.A.	63	18 (28.6)	N.A.	1.039 (0.549, 1.964) 0.9085	
>= 1	22	5 (22.7)	N.A.	26	3 (11.5)	N.A.	2.032 (0.486, 8.504) 0.3215	
TOBACCO USE								0.3505
NEVER SMOKED	9	2 (22.2)	N.A. (1.81, N.A.)	8	3 (37.5)	N.A. (1.08, N.A.)	0.517 (0.086, 3.107) 0.4633	
CURRENT/FORMER	79	23 (29.1)	N.A.	80	18 (22.5)	N.A.	1.308 (0.706, 2.423) 0.3932	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 5 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.8108
STAGE IB/II	36	11 (30.6)	N.A.	34	9 (26.5)	N.A.	1.107 (0.459, 2.672) 0.8232	
STAGE IIIA	52	14 (26.9)	N.A.	55	12 (21.8)	N.A.	1.277 (0.591, 2.761) 0.5327	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.7512
STAGE IB/II	32	10 (31.3)	N.A. (4.73, N.A.)	32	9 (28.1)	N.A.	1.059 (0.430, 2.608) 0.9034	
STAGE IIIA	56	15 (26.8)	N.A.	56	12 (21.4)	N.A.	1.284 (0.601, 2.743) 0.5167	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 6 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.1287
SQUAMOUS CELL CARCINOMA	47	15 (31.9)	N.A.	50	9 (18.0)	N.A.	1.868 (0.817, 4.269) 0.1327	
NON-SQUAMOUS	41	10 (24.4)	N.A.	39	12 (30.8)	N.A.	0.752 (0.325, 1.741) 0.5060	
PD-L1 STATUS (CLINICAL DATABASE) I								0.2016
1-49%	50	16 (32.0)	N.A.	47	9 (19.1)	N.A.	1.711 (0.756, 3.873) 0.1917	
>= 50%	38	9 (23.7)	N.A.	42	12 (28.6)	N.A.	0.784 (0.330, 1.862) 0.5804	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 7 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB I								0.3334
>= 12.3 MUT/MB	20	7 (35.0)	N.A. (3.22, N.A.)	24	9 (37.5)	N.A. (3.06, N.A.)	0.842 (0.313, 2.262) 0.7330	
< 12.3 MUT/MB	26	5 (19.2)	N.A.	22	5 (22.7)	N.A.	0.816 (0.236, 2.820) 0.7476	
NOT EVALUABLE/NOT REPORTED	42	13 (31.0)	N.A.	43	7 (16.3)	N.A.	2.050 (0.818, 5.139) 0.1182	
TUMOR TISSUE TMB II								0.1204
OVERALL EVALUABLE	46	12 (26.1)	N.A.	46	14 (30.4)	N.A.	0.794 (0.367, 1.718) 0.5587	
NOT EVALUABLE/NOT REPORTED	42	13 (31.0)	N.A.	43	7 (16.3)	N.A.	2.050 (0.818, 5.139) 0.1182	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 8 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.8252
CISPLATIN	61	19 (31.1)	N.A.	66	16 (24.2)	N.A.	1.304 (0.670, 2.536) 0.4336	
CARBOPLATIN	21	5 (23.8)	N.A. (4.73, N.A.)	19	4 (21.1)	N.A.	1.130 (0.303, 4.209) 0.8553	
TYPE OF PLATINUM THERAPY II								0.8578
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	20 (30.3)	N.A.	70	17 (24.3)	N.A.	1.264 (0.662, 2.413) 0.4762	
CARBOPLATIN	21	5 (23.8)	N.A. (4.73, N.A.)	19	4 (21.1)	N.A.	1.130 (0.303, 4.209) 0.8553	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Protocol: CA209816 Page 9 of 9

Serious Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	25 (28.4)	N.A.	65	16 (24.6)	N.A.	1.152 (0.615, 2.158) 0.6590	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	5 (20.8)	N.A.	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:16

Anhang 4-G 5.2.3.4: Subgruppenanalysen für den Endpunkt zum Therapieabbruch führende UE ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	11 (12.5)	N.A.	89	14 (15.7)	N.A. (7.46, N.A.)	0.843 (0.381, 1.863) 0.6715	
AGE CATEGORIZATION I								0.8789
< 65	47	4 (8.5)	N.A.	42	4 (9.5)	N.A.	0.908 (0.227, 3.631) 0.8915	
>= 65	41	7 (17.1)	N.A.	47	10 (21.3)	N.A. (6.47, N.A.)	0.848 (0.322, 2.234) 0.7376	
AGE CATEGORIZATION II								0.9309
< 65	47	4 (8.5)	N.A.	42	4 (9.5)	N.A.	0.908 (0.227, 3.631) 0.8915	
>= 65 AND < 75	36	5 (13.9)	N.A.	43	7 (16.3)	N.A. (6.47, N.A.)	0.907 (0.287, 2.870) 0.8679	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Protocol: CA209816 Page 2 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.6903
MALE	67	8 (11.9)	N.A.	65	11 (16.9)	N.A. (7.46, N.A.)	0.737 (0.294, 1.846) 0.5128	
FEMALE	21	3 (14.3)	N.A.	24	3 (12.5)	6.47 (6.47, N.A.)	1.159 (0.234, 5.750) 0.8562	
SEX (CRF)								0.7404
MALE	66	8 (12.1)	N.A.	65	11 (16.9)	N.A. (7.46, N.A.)	0.749 (0.299, 1.875) 0.5350	
FEMALE	22	3 (13.6)	N.A.	24	3 (12.5)	6.47 (6.47, N.A.)	1.112 (0.224, 5.515) 0.8964	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Protocol: CA209816 Page 3 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.1547
WHITE	37	5 (13.5)	N.A.	36	10 (27.8)	7.46 (6.47, N.A.)	0.511 (0.174, 1.501) 0.2128	
ASIAN	50	6 (12.0)	N.A.	52	4 (7.7)	N.A.	1.564 (0.441, 5.543) 0.4852	
REGION								0.0567
NORTH AMERICA	16	3 (18.8)	N.A.	21	3 (14.3)	7.46 (6.47, N.A.)	4.228 (0.440, 40.669) 0.1741	
EUROPE	18	2 (11.1)	N.A.	11	6 (54.5)	2.14 (0.72, N.A.)	0.149 (0.030, 0.747) 0.0076	
ASIA	50	6 (12.0)	N.A.	52	4 (7.7)	N.A.	1.564 (0.441, 5.543) 0.4852	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Protocol: CA209816 Page 4 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.3380
0	66	9 (13.6)	N.A.	63	9 (14.3)	N.A. (7.46, N.A.)	1.114 (0.434, 2.859) 0.8227	
>= 1	22	2 (9.1)	N.A. (1.87, N.A.)	26	5 (19.2)	N.A.	0.435 (0.084, 2.250) 0.3072	
TOBACCO USE								0.9896
NEVER SMOKED	9	1 (11.1)	N.A.	8	0	N.E.	N.E. 0.3458	
CURRENT/FORMER	79	10 (12.7)	N.A.	80	13 (16.3)	N.A. (7.46, N.A.)	0.834 (0.364, 1.910) 0.6671	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Protocol: CA209816 Page 5 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.4088
STAGE IB/II	36	5 (13.9)	N.A.	34	8 (23.5)	N.A. (6.47, N.A.)	0.608 (0.199, 1.861) 0.3783	
STAGE IIIA	52	6 (11.5)	N.A.	55	6 (10.9)	N.A. (7.46, N.A.)	1.189 (0.374, 3.776) 0.7694	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.7185
STAGE IB/II	32	4 (12.5)	N.A.	32	6 (18.8)	N.A. (6.47, N.A.)	0.720 (0.202, 2.566) 0.6105	
STAGE IIIA	56	7 (12.5)	N.A.	56	8 (14.3)	N.A. (7.46, N.A.)	0.932 (0.335, 2.590) 0.8921	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Protocol: CA209816 Page 6 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	 Subjects with Event n (%)	 KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	 Subjects with Event n (%)	 KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	 Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.1414
SQUAMOUS CELL CARCINOMA	47	9 (19.1)	N.A. (6.47, N.A.)	50	8 (16.0)	N.A. (6.47, N.A.)	1.335 (0.513, 3.470) 0.5524	
NON-SQUAMOUS	41	2 (4.9)	N.A.	39	6 (15.4)	N.A.	0.314 (0.063, 1.555) 0.1336	
PD-L1 STATUS (CLINICAL DATABASE) I								0.9423
1-49%	50	7 (14.0)	N.A. (6.47, N.A.)	47	8 (17.0)	N.A. (6.47, N.A.)	0.856 (0.310, 2.365) 0.7635	
>= 50%	38	4 (10.5)	N.A. (7.46, N.A.)	42	6 (14.3)	N.A. (7.46, N.A.)	0.821 (0.228, 2.956) 0.7615	
TUMOR TISSUE TMB I								N.M.E.
>= 12.3 MUT/MB	20	2 (10.0)	N.M.E.	24	7 (29.2)	N.M.E.	N.M.E.	
< 12.3 MUT/MB	26	5 (19.2)	N.M.E.	22	3 (13.6)	N.M.E.	N.M.E.	
NOT EVALUABLE/NOT REPORTED	42	4 (9.5)	N.M.E.	43	4 (9.3)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Protocol: CA209816 Page 7 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB II								0.7078
OVERALL EVALUABLE	46	7 (15.2)	N.A.	46	10 (21.7)	N.A. (7.46, N.A.)	0.775 (0.292, 2.056) 0.6067	
NOT EVALUABLE/NOT REPORTED	42	4 (9.5)	N.A.	43	4 (9.3)	N.A.	1.027 (0.257, 4.106) 0.9704	
TYPE OF PLATINUM THERAPY I								0.9898
CISPLATIN	61	7 (11.5)	N.A.	66	10 (15.2)	N.A.	0.739 (0.281, 1.943) 0.5379	
CARBOPLATIN	21	0	N.E.	19	4 (21.1)	7.46 (6.47, N.A.)	N.E. 0.1318	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Protocol: CA209816 Page 8 of 8

Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment
Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

AEs Leading to Discontinuation of Study Treatment Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY II								0.9890
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	10 (15.2)	N.A.	70	10 (14.3)	N.A.	1.064 (0.443, 2.557) 0.8895	
CARBOPLATIN	21	0	N.E.	19	4 (21.1)	7.46 (6.47, N.A.)	N.E. 0.1318	
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	11 (12.5)	N.A.	65	11 (16.9)	N.A. (7.46, N.A.)	0.806 (0.347, 1.872) 0.6153	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	3 (12.5)	N.A.	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr1525.sas 21MAR2023:17:16:25

Anhang 4-G 5.3: Subgruppenanalysen zu Endpunkten dieses Anhangs aus CA209-816 (PD-L1-positive Population)

Matrix der durchgeführten Subgruppenanalysen (PD-L1-positive Population)

Endpunkte Studie CA209-816	**Altersgruppe I**[1]	**Altersgruppe II**[1]	**Geschlecht gemäß IRT**	**Geschlecht gemäß CRF**	**Ethnie**	**Region**	**ECOG Performance Status**	**Raucherstatus**	**Krankheitsstadium zu Studienbeginn gemäß IRT**	**Krankheitsstadium zu Studienbeginn gemäß CRF**	**Tumorhistologie**	**PD-L1-Status**	**Tumorgewebe-TMB-Status I**	**Tumorgewebe-TMB-Status II**	**Art der Platinkomponente I**	**Art der Platinkomponente II**	**Chemotherapieregime im Vergleichsarm**
Endpunkte Verträglichkeit – UE von speziellem Interesse (UESI)																	
jegliche spezifische immunvermittelte UE	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
jegliche spezifische UE	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
jegliche weitere UE von speziellem Interesse[2]	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Endpunkte Verträglichkeit – häufige UE auf SOC/PT-Ebene[3]																	
UE Neutropenie (PT)	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
UE Ausschlag (PT)	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Schwere UE Erkrankungen des Blutes und des Lymphsystems (SOC)	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Schwere UE Neutropenie (PT)	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○

Ergänzende Analysen

Endpunkte Studie CA209-816	**Altersgruppe I[(1)]**	**Altersgruppe II[(1)]**	**Geschlecht gemäß IRT**	**Geschlecht gemäß CRF**	**Ethnie**	**Region**	**ECOG Performance Status**	**Raucherstatus**	**Krankheitsstadium zu Studienbeginn gemäß IRT**	**Krankheitsstadium zu Studienbeginn gemäß CRF**	**Tumorhistologie**	**PD-L1-Status**	**Tumorgewebe-TMB-Status I**	**Tumorgewebe-TMB-Status II**	**Art der Platinkomponente I**	**Art der Platinkomponente II**	**Chemotherapieregime im Vergleichsarm**
Schwere UE Stoffwechsel- und Ernährungsstörungen (SOC)	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○

CRF = Datenerhebungsformular (Case Report Form); ECOG = Eastern Cooperative Oncology Group; IRT = Interaktive Antworttechnologie (Interactive Response Technology); n.d. = Nicht durchgeführt; OESI = Weitere UE von besonderem Interesse (Other Events of Special Interest); PD-L1 = Programmed Death Ligand-1; PT = Preferred Term; SOC = Systemorganklasse (System Organ Class); TMB = Tumormutationslast (Tumor Mutation Burden); UE = Unerwünschte(s) Ereignis(se); UESI = Unerwünschte(s) Ereignis(se) von speziellem Interesse; vs. = Versus

● = Gemäß Studienprotokoll geplante Subgruppenanalyse; ○ = Für das vorliegende Dossier durchgeführte Subgruppenanalyse;

(1) Das gemäß Studienprotokoll definierte Subgruppenmerkmal Altersgruppe < 65, ≥ 65 vs. < 75, ≥ 75 vs. <85, ≥ 85, ≥ 75, ≥65 enthält die Subgruppenmerkmale Altersgruppe I und II.

(2) Für die Endpunkte „weitere UE von speziellem Interesse (OESI)“ ist die Anzahl der Patienten mit einem Ereignis geringer als 10 Patienten. Daher werden für diese Endpunkte keine Subgruppenanalysen durchgeführt.

(3) Subgruppenanalysen werden nur für diejenigen UE auf SOC/PT-Ebene dargestellt, für welche die Gesamtanalyse gemäß p-Wert statistisch signifikant war.

Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie CA209-816 und alle Effektmodifikatoren (PD-L1-positive Population; 1. Teil)

Endpunkte[(1)] Studie CA209-816	**Altersgruppe I**	**Altersgruppe II**	**Geschlecht gemäß IRT**	**Geschlecht gemäß CRF**	**Ethnie**	**Region**	**ECOG Performance Status**	**Raucherstatus**
Endpunkte Verträglichkeit – UE von speziellem Interesse (UESI)[(2)]								
jegliche spezifische immunvermittelte UE	0,9932	0,9941	0,2945	0,2760	0,9926	>0,9999	0,9931	0,2280
jegliche spezifische UE	0,8375	0,9634	0,8421	0,9280	0,4885	0,5548	0,8884	0,9940
jegliche weitere UE von speziellem Interesse	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Endpunkte Verträglichkeit – häufige UE auf SOC/PT-Ebene[(2)]								
UE Neutropenie (PT)	0,0976	0,1658	0,9895	0,9893	0,6963	0,4858	0,2578	0,9887
UE Ausschlag (PT)	N.M.E.	N.M.E.	0,7759	0,7421	0,7905	0,6205	0,8196	0,9997
Schwere UE Erkrankungen des Blutes und des Lymphsystems (SOC)	0,2664	0,2211	0,9885	0,9883	0,2581	0,3930	0,0850	0,5827
Schwere UE Neutropenie (PT)	0,0736	0,0968	0,9917	0,9915	0,4251	0,5810	0,9899	0,9904
Schwere UE Stoffwechsel- und Ernährungsstörungen (SOC)	N.M.E.	N.M.E.	N.M.E.	N.M.E.	0,9933	>0,9999	N.M.E.	0,9933

Endpunkte[(1)] Studie CA209-816	**Altersgruppe I**	**Altersgruppe II**	**Geschlecht gemäß IRT**	**Geschlecht gemäß CRF**	**Ethnie**	**Region**	**ECOG Performance Status**	**Raucherstatus**

CRF = Datenerhebungsformular (Case Report Form); ECOG = Eastern Cooperative Oncology Group; IRT = Interaktive Antworttechnologie (Interactive Response Technology); N.A. = Nicht anwendbar bzw. nicht erreicht; n.d. = Nicht durchgeführt; N.M.E. = Nicht sinnvoll schätzbar; OESI = Weitere UE von besonderem Interesse (Other Events of Special Interest); PD-L1 = Programmed Death Ligand-1; PT = Preferred Term; SOC = Systemorganklasse (System Organ Class); TMB = Tumormutationslast (Tumor Mutation Burden); UE = Unerwünschte(s) Ereignis(se); UESI = Unerwünschte(s) Ereignis(se) von speziellem Interesse; vs. = Versus

(1) Angegebene Werte sind p-Werte. p-Werte < 0,05 werden mit einem Stern und **fett** markiert (Beleg für eine Interaktion).

(2) Zeit bis zum ersten Auftreten des UE.

Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie CA209-816 und alle Effektmodifikatoren (PD-L1-positive Population; 2. Teil)

Endpunkte[1] Studie CA209-816	**Krankheitsstadium zu Studienbeginn gemäß IRT**	**Krankheitsstadium zu Studienbeginn gemäß CRF**	**Tumorhistologie**	**PD-L1-Status**	**Tumorgewebe-TMB-Status I**	**Tumorgewebe-TMB-Status II**	**Art der Platinkomponente I**	**Art der Platinkomponente II**	**Chemotherapieregime im Vergleichsarm**
Endpunkte Verträglichkeit – UE von speziellem Interesse (UESI)[2]									
jegliche spezifische immunvermittelte UE	N.M.E.	N.M.E.	0,9912	N.M.E.	N.M.E.	N.M.E.	0,5179	0,4791	N.A.
jegliche spezifische UE	0,1045	0,2191	0,7863	0,4712	0,9948	0,9929	0,3803	0,3583	N.A.
jegliche weitere UE von speziellem Interesse	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Endpunkte Verträglichkeit – häufige UE auf SOC/PT-Ebene[2]									
UE Neutropenie (PT)	0,6814	0,2811	0,9703	0,8174	0,2929	0,8002	0,2612	0,2224	N.A.
UE Ausschlag (PT)	0,9936	0,9935	N.M.E.	0,6630	N.M.E.	N.M.E.	0,9923	0,9924	N.A.
Schwere UE Erkrankungen des Blutes und des Lymphsystems (SOC)	0,7409	0,5751	0,0544	0,7102	0,4591	0,8491	0,1917	0,2081	N.A.
Schwere UE Neutropenie (PT)	0,8703	0,3986	0,3828	0,1126	0,3741	0,4610	0,2222	0,2159	N.A.
Schwere UE Stoffwechsel- und Ernährungsstörungen (SOC)	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.

Endpunkte[(1)] Studie CA209-816	**Krankheitsstadium zu Studienbeginn gemäß IRT**	**Krankheitsstadium zu Studienbeginn gemäß CRF**	**Tumorhistologie**	**PD-L1-Status**	**Tumorgewebe-TMB-Status I**	**Tumorgewebe-TMB-Status II**	**Art der Platinkomponente I**	**Art der Platinkomponente II**	**Chemotherapieregime im Vergleichsarm**

CRF = Datenerhebungsformular (Case Report Form); ECOG = Eastern Cooperative Oncology Group; IRT = Interaktive Antworttechnologie (Interactive Response Technology); N.A. = Nicht anwendbar bzw. nicht erreicht; n.d. = Nicht durchgeführt; N.M.E. = Nicht sinnvoll schätzbar; OESI = Weitere UE von besonderem Interesse (Other Events of Special Interest); PD-L1 = Programmed Death Ligand-1; PT = Preferred Term; SOC = Systemorganklasse (System Organ Class); TMB = Tumormutationslast (Tumor Mutation Burden); UE = Unerwünschte(s) Ereignis(se); UESI = Unerwünschte(s) Ereignis(se) von speziellem Interesse; vs. = Versus

(1) Angegebene Werte sind p-Werte. p-Werte < 0,05 werden mit einem Stern und **fett** markiert (Beleg für eine Interaktion).

(2) Zeit bis zum ersten Auftreten des UE.

Anhang 4-G 5.3.1: Subgruppenanalysen für Endpunkte spezifische immunvermittelte UE aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

Immune-mediated Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Arm C vs. Concurrent Arm B Test for Interaction P-value (4)(5)
OVERALL	88	14 (15.9)	N.A.	89	2 (2.2)	N.A.	7.542 (1.714, 33.186) 0.0016	
AGE CATEGORIZATION I								0.9932
< 65	47	9 (19.1)	N.A.	42	2 (4.8)	N.A.	4.430 (0.957, 20.511) 0.0372	
>= 65	41	5 (12.2)	N.A.	47	0	N.E.	N.E. 0.0159	
AGE CATEGORIZATION II								0.9941
< 65	47	9 (19.1)	N.A.	42	2 (4.8)	N.A.	4.430 (0.957, 20.511) 0.0372	
>= 65 AND < 75	36	3 (8.3)	N.A.	43	0	N.E.	N.E. 0.0597	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Protocol: CA209816 Page 2 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

Immune-mediated Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.2945
MALE	67	12 (17.9)	N.A.	65	1 (1.5)	N.A.	12.466 (1.621, 95.879) 0.0018	
FEMALE	21	2 (9.5)	N.A.	24	1 (4.2)	N.A.	2.333 (0.212, 25.734) 0.4760	
SEX (CRF)								0.2760
MALE	66	12 (18.2)	N.A.	65	1 (1.5)	N.A.	12.680 (1.649, 97.523) 0.0016	
FEMALE	22	2 (9.1)	N.A.	24	1 (4.2)	N.A.	2.222 (0.201, 24.506) 0.5032	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Protocol: CA209816 Page 3 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Immune-mediated Adverse Events 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								0.9926
WHITE	37	2 (5.4)	N.A.	36	0	N.E.	N.E. 0.1601	
ASIAN	50	12 (24.0)	N.A.	52	2 (3.8)	N.A.	6.965 (1.559, 31.125) 0.0031	
REGION								>0.9999
NORTH AMERICA	16	2 (12.5)	N.A.	21	0	N.E.	N.E. 0.0996	
EUROPE	18	0	N.E.	11	0	N.E.	N.E. N.E.	
ASIA	50	12 (24.0)	N.A.	52	2 (3.8)	N.A.	6.965 (1.559, 31.125) 0.0031	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Protocol: CA209816 Page 4 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

Immune-mediated Adverse Events Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.9931
0	66	13 (19.7)	N.A.	63	2 (3.2)	N.A.	6.738 (1.520, 29.865) 0.0036	
>= 1	22	1 (4.5)	N.A.	26	0	N.E.	N.E. 0.2770	
TOBACCO USE								0.2280
NEVER SMOKED	9	2 (22.2)	N.A. (0.89, N.A.)	8	1 (12.5)	N.A. (3.81, N.A.)	1.840 (0.167, 20.312) 0.6132	
CURRENT/FORMER	79	12 (15.2)	N.A.	80	1 (1.3)	N.A.	12.875 (1.674, 99.019) 0.0015	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Protocol: CA209816 Page 5 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Immune-mediated Adverse Events 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 (IRT)								N.M.E.
STAGE IB/II	36	7 (19.4)	N.M.E.	34	0	N.M.E.	N.M.E.	
STAGE IIIA	52	7 (13.5)	N.M.E.	55	2 (3.6)	N.M.E.	N.M.E.	
DISEASE STAGE AT STUDY ENTRY (CRF)								N.M.E.
STAGE IB/II	32	7 (21.9)	N.M.E.	32	0	N.M.E.	N.M.E.	
STAGE IIIA	56	7 (12.5)	N.M.E.	56	2 (3.6)	N.M.E.	N.M.E.	
CELL TYPE AT STUDY ENTRY								0.9912
SQUAMOUS CELL CARCINOMA	47	10 (21.3)	N.A.	50	2 (4.0)	N.A.	5.915 (1.295, 27.005) 0.0091	
NON-SQUAMOUS	41	4 (9.8)	N.A.	39	0	N.E.	N.E. 0.0499	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Protocol: CA209816 Page 6 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

Immune-mediated Adverse Events Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 STATUS (CLINICAL DATABASE) I								N.M.E.
1-49%	50	7 (14.0)	N.M.E.	47	1 (2.1)	N.M.E.	N.M.E.	
>= 50%	38	7 (18.4)	N.M.E.	42	1 (2.4)	N.M.E.	N.M.E.	
TUMOR TISSUE TMB I								N.M.E.
>= 12.3 MUT/MB	20	4 (20.0)	N.M.E.	24	0	N.M.E.	N.M.E.	
< 12.3 MUT/MB	26	4 (15.4)	N.M.E.	22	1 (4.5)	N.M.E.	N.M.E.	
NOT EVALUABLE/NOT REPORTED	42	6 (14.3)	N.M.E.	43	1 (2.3)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Protocol: CA209816 Page 7 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

Immune-mediated Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB II								N.M.E.
OVERALL EVALUABLE	46	8 (17.4)	N.M.E.	46	1 (2.2)	N.M.E.	N.M.E.	
NOT EVALUABLE/NOT REPORTED	42	6 (14.3)	N.M.E.	43	1 (2.3)	N.M.E.	N.M.E.	
TYPE OF PLATINUM THERAPY I								0.5179
CISPLATIN	61	9 (14.8)	N.A.	66	1 (1.5)	N.A.	10.319 (1.307, 81.460) 0.0059	
CARBOPLATIN	21	4 (19.0)	N.A.	19	1 (5.3)	N.A.	3.740 (0.418, 33.473) 0.2051	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Protocol: CA209816 Page 8 of 8

Immune-mediated Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any IMAEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Immune-mediated Adverse Events Category: Any Immune-mediated Adverse Events

Immune-mediated Adverse Events Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY II								0.4791
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	10 (15.2)	N.A.	70	1 (1.4)	N.A.	11.297 (1.446, 88.259) 0.0035	
CARBOPLATIN	21	4 (19.0)	N.A.	19	1 (5.3)	N.A.	3.740 (0.418, 33.473) 0.2051	
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	14 (15.9)	N.A.	65	1 (1.5)	N.A.	10.983 (1.444, 83.514) 0.0036	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	1 (4.2)	N.A.	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae-ebr1525.sas 22MAR2023:17:03:12

Anhang 4-G 5.3.2: Subgruppenanalysen für Endpunkte spezifische UE (select UE) aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	49 (55.7)	2.45 (0.53, N.A.)	89	44 (49.4)	5.19 (1.68, N.A.)	1.300 (0.865, 1.953) 0.2068	
AGE CATEGORIZATION I								0.8375
< 65	47	27 (57.4)	2.37 (0.39, N.A.)	42	22 (52.4)	3.68 (1.38, N.A.)	1.363 (0.776, 2.395) 0.2831	
>= 65	41	22 (53.7)	2.53 (0.49, N.A.)	47	22 (46.8)	N.A. (1.58, N.A.)	1.228 (0.679, 2.218) 0.4985	
AGE CATEGORIZATION II								0.9634
< 65	47	27 (57.4)	2.37 (0.39, N.A.)	42	22 (52.4)	3.68 (1.38, N.A.)	1.363 (0.776, 2.395) 0.2831	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 2 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events Subgroup	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
>= 65 AND < 75	36	19 (52.8)	3.43 (0.49, N.A.)	43	19 (44.2)	N.A. (2.27, N.A.)	1.318 (0.698, 2.492) 0.3964	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 3 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.8421
MALE	67	38 (56.7)	1.38 (0.46, N.A.)	65	32 (49.2)	N.A. (1.51, N.A.)	1.331 (0.831, 2.130) 0.2328	
FEMALE	21	11 (52.4)	2.92 (0.26, N.A.)	24	12 (50.0)	5.19 (1.38, N.A.)	1.169 (0.515, 2.651) 0.7153	
SEX (CRF)								0.9280
MALE	66	37 (56.1)	1.63 (0.46, N.A.)	65	32 (49.2)	N.A. (1.51, N.A.)	1.315 (0.819, 2.111) 0.2566	
FEMALE	22	12 (54.5)	2.86 (0.26, N.A.)	24	12 (50.0)	5.19 (1.38, N.A.)	1.233 (0.553, 2.745) 0.6133	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 4 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.4885
WHITE	37	16 (43.2)	N.A. (0.49, N.A.)	36	16 (44.4)	N.A. (0.72, N.A.)	1.064 (0.532, 2.128) 0.8552	
ASIAN	50	32 (64.0)	1.63 (0.43, 4.34)	52	28 (53.8)	3.35 (1.51, N.A.)	1.460 (0.878, 2.426) 0.1426	
REGION								0.5548
NORTH AMERICA	16	10 (62.5)	0.51 (0.20, N.A.)	21	11 (52.4)	5.19 (0.72, N.A.)	1.515 (0.641, 3.580) 0.3292	
EUROPE	18	5 (27.8)	N.A. (0.72, N.A.)	11	4 (36.4)	N.A. (0.20, N.A.)	0.759 (0.204, 2.834) 0.6818	
ASIA	50	32 (64.0)	1.63 (0.43, 4.34)	52	28 (53.8)	3.35 (1.51, N.A.)	1.460 (0.878, 2.426) 0.1426	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 5 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.8884
0	66	40 (60.6)	1.63 (0.46, N.A.)	63	35 (55.6)	3.02 (1.51, N.A.)	1.263 (0.802, 1.989) 0.3097	
>= 1	22	9 (40.9)	N.A. (0.26, N.A.)	26	9 (34.6)	N.A. (1.38, N.A.)	1.355 (0.537, 3.416) 0.5216	
TOBACCO USE								0.9940
NEVER SMOKED	9	4 (44.4)	N.A. (0.33, N.A.)	8	3 (37.5)	N.A. (0.26, N.A.)	1.304 (0.291, 5.849) 0.7281	
CURRENT/FORMER	79	45 (57.0)	1.87 (0.49, N.A.)	80	41 (51.3)	3.68 (1.58, N.A.)	1.286 (0.842, 1.964) 0.2445	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 6 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.1045
STAGE IB/II	36	23 (63.9)	0.99 (0.33, N.A.)	34	14 (41.2)	N.A. (0.92, N.A.)	1.982 (1.017, 3.861) 0.0403	
STAGE IIIA	52	26 (50.0)	4.34 (0.53, N.A.)	55	30 (54.5)	3.02 (1.38, N.A.)	0.983 (0.581, 1.663) 0.9465	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.2191
STAGE IB/II	32	20 (62.5)	0.99 (0.33, N.A.)	32	14 (43.8)	N.A. (0.92, N.A.)	1.834 (0.924, 3.640) 0.0778	
STAGE IIIA	56	29 (51.8)	3.63 (0.53, N.A.)	56	30 (53.6)	3.02 (1.38, N.A.)	1.051 (0.631, 1.752) 0.8514	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 7 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.7863
SQUAMOUS CELL CARCINOMA	47	31 (66.0)	0.72 (0.30, 2.79)	50	29 (58.0)	3.01 (0.72, N.A.)	1.414 (0.852, 2.347) 0.1786	
NON-SQUAMOUS	41	18 (43.9)	N.A. (0.69, N.A.)	39	15 (38.5)	N.A. (2.27, N.A.)	1.228 (0.619, 2.437) 0.5533	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 8 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 STATUS (CLINICAL DATABASE) I								0.4712
1-49%	50	29 (58.0)	2.45 (0.39, N.A.)	47	22 (46.8)	N.A. (2.27, N.A.)	1.483 (0.852, 2.582) 0.1578	
>= 50%	38	20 (52.6)	2.33 (0.49, N.A.)	42	22 (52.4)	3.68 (0.92, N.A.)	1.106 (0.603, 2.027) 0.7577	
TUMOR TISSUE TMB I								0.9948
>= 12.3 MUT/MB	20	9 (45.0)	N.A. (0.30, N.A.)	24	9 (37.5)	N.A. (1.58, N.A.)	1.273 (0.505, 3.210) 0.6034	
< 12.3 MUT/MB	26	16 (61.5)	0.87 (0.26, N.A.)	22	13 (59.1)	2.99 (0.33, N.A.)	1.231 (0.592, 2.561) 0.5706	
NOT EVALUABLE/NOT REPORTED	42	24 (57.1)	1.87 (0.49, N.A.)	43	22 (51.2)	3.68 (1.35, N.A.)	1.312 (0.735, 2.340) 0.3609	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 9 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB II								0.9929
OVERALL EVALUABLE	46	25 (54.3)	2.66 (0.33, N.A.)	46	22 (47.8)	N.A. (1.58, N.A.)	1.283 (0.723, 2.277) 0.3909	
NOT EVALUABLE/NOT REPORTED	42	24 (57.1)	1.87 (0.49, N.A.)	43	22 (51.2)	3.68 (1.35, N.A.)	1.312 (0.735, 2.340) 0.3609	
TYPE OF PLATINUM THERAPY I								0.3803
CISPLATIN	61	30 (49.2)	N.A. (0.53, N.A.)	66	27 (40.9)	N.A. (2.99, N.A.)	1.394 (0.829, 2.345) 0.2113	
CARBOPLATIN	21	14 (66.7)	1.38 (0.43, N.A.)	19	14 (73.7)	1.38 (0.30, 5.19)	0.941 (0.448, 1.976) 0.8768	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Protocol: CA209816 Page 10 of 10

Select Adverse Events Over the Entire Study Period
Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY II								0.3583
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	34 (51.5)	2.79 (0.49, N.A.)	70	30 (42.9)	N.A. (2.56, N.A.)	1.403 (0.858, 2.293) 0.1769	
CARBOPLATIN	21	14 (66.7)	1.38 (0.43, N.A.)	19	14 (73.7)	1.38 (0.30, 5.19)	0.941 (0.448, 1.976) 0.8768	
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	49 (55.7)	2.45 (0.53, N.A.)	65	35 (53.8)	3.68 (1.51, N.A.)	1.150 (0.745, 1.775) 0.5277	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	9 (37.5)	N.A. (1.38, N.A.)	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Arm C over Conc. Arm B. (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: 25.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae-ebr1525.sas 22MAR2023:15:18:02

Anhang 4-G 5.3.3: Subgruppenanalysen für Endpunkte Unerwünschte Ereignisse auf SOC/PT-Ebene aus CA209-816 – Zeit bis zum ersten Auftreten des UE (PD-L1-positive Population)

Anhang 4-G 5.3.3.1: Subgruppenanalysen für Endpunkt Jegliche UE auf SOC/PT-Ebene aus CA209-816 (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	9 (10.2)	N.A.	89	20 (22.5)	N.A.	0.425 (0.193, 0.933) 0.0280	
AGE CATEGORIZATION I								0.0976
< 65	47	7 (14.9)	N.A.	42	8 (19.0)	N.A.	0.778 (0.282, 2.146) 0.6268	
>= 65	41	2 (4.9)	N.A.	47	12 (25.5)	N.A.	0.169 (0.038, 0.757) 0.0083	
AGE CATEGORIZATION II								0.1658
< 65	47	7 (14.9)	N.A.	42	8 (19.0)	N.A.	0.778 (0.282, 2.146) 0.6268	
>= 65 AND < 75	36	2 (5.6)	N.A.	43	10 (23.3)	N.A.	0.214 (0.047, 0.979) 0.0284	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 2 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.9895
MALE	67	9 (13.4)	N.A.	65	18 (27.7)	N.A.	0.446 (0.200, 0.993) 0.0427	
FEMALE	21	0	N.E.	24	2 (8.3)	N.A.	N.E. 0.1812	
SEX (CRF)								0.9893
MALE	66	9 (13.6)	N.A.	65	18 (27.7)	N.A.	0.453 (0.204, 1.010) 0.0473	
FEMALE	22	0	N.E.	24	2 (8.3)	N.A.	N.E. 0.1711	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 3 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.6963
WHITE	37	3 (8.1)	N.A.	36	9 (25.0)	N.A.	0.300 (0.081, 1.109) 0.0561	
ASIAN	50	5 (10.0)	N.A.	52	11 (21.2)	N.A.	0.443 (0.154, 1.276) 0.1205	
REGION								0.4858
NORTH AMERICA	16	2 (12.5)	N.A.	21	0	N.E.	N.E. 0.0938	
EUROPE	18	2 (11.1)	N.A.	11	7 (63.6)	1.64 (0.72, N.A.)	0.112 (0.023, 0.548) 0.0012	
ASIA	50	5 (10.0)	N.A.	52	11 (21.2)	N.A.	0.443 (0.154, 1.276) 0.1205	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 4 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Adverse Events Subgroups	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 PS								0.2578
0	66	8 (12.1)	N.A.	63	13 (20.6)	N.A.	0.565 (0.234, 1.362) 0.1992	
>= 1	22	1 (4.5)	N.A.	26	7 (26.9)	N.A. (4.90, N.A.)	0.148 (0.018, 1.205) 0.0386	
TOBACCO USE								0.9887
NEVER SMOKED	9	0	N.E.	8	1 (12.5)	N.A. (0.39, N.A.)	N.E. 0.2888	
CURRENT/FORMER	79	9 (11.4)	N.A.	80	18 (22.5)	N.A.	0.476 (0.214, 1.060) 0.0631	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 5 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Adverse Events Subgroups	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 (IRT)								0.6814
STAGE IB/II	36	6 (16.7)	N.A.	34	11 (32.4)	N.A. (1.68, N.A.)	0.469 (0.173, 1.269) 0.1267	
STAGE IIIA	52	3 (5.8)	N.A.	55	9 (16.4)	N.A.	0.333 (0.090, 1.230) 0.0829	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.2811
STAGE IB/II	32	6 (18.8)	N.A.	32	9 (28.1)	N.A.	0.624 (0.222, 1.753) 0.3656	
STAGE IIIA	56	3 (5.4)	N.A.	56	11 (19.6)	N.A.	0.252 (0.070, 0.905) 0.0224	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 6 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.9703
SQUAMOUS CELL CARCINOMA	47	6 (12.8)	N.A.	50	14 (28.0)	N.A.	0.434 (0.167, 1.130) 0.0780	
NON-SQUAMOUS	41	3 (7.3)	N.A.	39	6 (15.4)	N.A.	0.437 (0.109, 1.747) 0.2293	
PD-L1 STATUS (CLINICAL DATABASE) I								0.8174
1-49%	50	5 (10.0)	N.A.	47	11 (23.4)	N.A.	0.390 (0.135, 1.122) 0.0700	
>= 50%	38	4 (10.5)	N.A.	42	9 (21.4)	N.A.	0.476 (0.146, 1.544) 0.2058	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 7 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Adverse Events Subgroups	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)
TUMOR TISSUE TMB I								0.2929
>= 12.3 MUT/MB	20	3 (15.0)	N.A.	24	3 (12.5)	N.A.	1.195 (0.241, 5.925) 0.8267	
< 12.3 MUT/MB	26	1 (3.8)	N.A.	22	5 (22.7)	N.A.	0.150 (0.018, 1.285) 0.0457	
NOT EVALUABLE/NOT REPORTED	42	5 (11.9)	N.A.	43	12 (27.9)	N.A.	0.396 (0.139, 1.124) 0.0711	
TUMOR TISSUE TMB II								0.8002
OVERALL EVALUABLE	46	4 (8.7)	N.A.	46	8 (17.4)	N.A.	0.468 (0.141, 1.553) 0.2048	
NOT EVALUABLE/NOT REPORTED	42	5 (11.9)	N.A.	43	12 (27.9)	N.A.	0.396 (0.139, 1.124) 0.0711	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 8 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Adverse Events Subgroups	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)
TYPE OF PLATINUM THERAPY I								0.2612
CISPLATIN	61	5 (8.2)	N.A.	66	15 (22.7)	N.A.	0.330 (0.120, 0.910) 0.0242	
CARBOPLATIN	21	4 (19.0)	N.A.	19	4 (21.1)	N.A.	0.902 (0.226, 3.607) 0.8840	
TYPE OF PLATINUM THERAPY II								0.2224
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	5 (7.6)	N.A.	70	16 (22.9)	N.A.	0.303 (0.111, 0.827) 0.0135	
CARBOPLATIN	21	4 (19.0)	N.A.	19	4 (21.1)	N.A.	0.902 (0.226, 3.607) 0.8840	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 9 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Adverse Events Subgroups	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)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	9 (10.2)	N.A.	65	12 (18.5)	N.A.	0.528 (0.222, 1.253) 0.1417	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	8 (33.3)	N.A. (1.28, N.A.)	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 10 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	12 (13.6)	N.A.	89	4 (4.5)	N.A.	3.200 (1.031, 9.925) 0.0332	
AGE CATEGORIZATION I								N.M.E.
< 65	47	8 (17.0)	N.M.E.	42	1 (2.4)	N.M.E.	N.M.E.	
>= 65	41	4 (9.8)	N.M.E.	47	3 (6.4)	N.M.E.	N.M.E.	
AGE CATEGORIZATION II								N.M.E.
< 65	47	8 (17.0)	N.M.E.	42	1 (2.4)	N.M.E.	N.M.E.	
>= 65 AND < 75	36	4 (11.1)	N.M.E.	43	3 (7.0)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 11 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.7759
MALE	67	10 (14.9)	N.A.	65	3 (4.6)	N.A.	3.464 (0.953, 12.595) 0.0443	
FEMALE	21	2 (9.5)	N.A.	24	1 (4.2)	N.A.	2.293 (0.208, 25.299) 0.4830	
SEX (CRF)								0.7421
MALE	66	10 (15.2)	N.A.	65	3 (4.6)	N.A.	3.516 (0.967, 12.784) 0.0415	
FEMALE	22	2 (9.1)	N.A.	24	1 (4.2)	N.A.	2.186 (0.198, 24.120) 0.5097	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 12 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.7905
WHITE	37	4 (10.8)	N.A.	36	1 (2.8)	N.A.	4.002 (0.447, 35.808) 0.1784	
ASIAN	50	8 (16.0)	N.A.	52	3 (5.8)	N.A.	2.937 (0.779, 11.075) 0.0946	
REGION								0.6205
NORTH AMERICA	16	3 (18.8)	N.A.	21	0	N.E.	N.E. 0.0402	
EUROPE	18	1 (5.6)	N.A.	11	1 (9.1)	N.A.	0.605 (0.038, 9.694) 0.7202	
ASIA	50	8 (16.0)	N.A.	52	3 (5.8)	N.A.	2.937 (0.779, 11.075) 0.0946	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 13 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.8196
0	66	10 (15.2)	N.A.	63	3 (4.8)	N.A.	3.391 (0.932, 12.336) 0.0487	
>= 1	22	2 (9.1)	N.A.	26	1 (3.8)	N.A.	2.479 (0.225, 27.345) 0.4433	
TOBACCO USE								0.9997
NEVER SMOKED	9	0	N.E.	8	0	N.E.	N.E. N.E.	
CURRENT/FORMER	79	12 (15.2)	N.A.	80	4 (5.0)	N.A.	3.214 (1.036, 9.970) 0.0323	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 14 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.9936
STAGE IB/II	36	3 (8.3)	N.A.	34	0	N.E.	N.E. 0.0877	
STAGE IIIA	52	9 (17.3)	N.A. (5.91, N.A.)	55	4 (7.3)	N.A.	2.545 (0.782, 8.277) 0.1074	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.9935
STAGE IB/II	32	3 (9.4)	N.A.	32	0	N.E.	N.E. 0.0784	
STAGE IIIA	56	9 (16.1)	N.A.	56	4 (7.1)	N.A.	2.339 (0.720, 7.598) 0.1449	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 15 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								N.M.E.
SQUAMOUS CELL CARCINOMA	47	7 (14.9)	N.M.E.	50	2 (4.0)	N.M.E.	N.M.E.	
NON-SQUAMOUS	41	5 (12.2)	N.M.E.	39	2 (5.1)	N.M.E.	N.M.E.	
PD-L1 STATUS (CLINICAL DATABASE) I								0.6630
1-49%	50	8 (16.0)	N.A.	47	2 (4.3)	N.A.	3.976 (0.844, 18.738) 0.0589	
>= 50%	38	4 (10.5)	N.A.	42	2 (4.8)	N.A.	2.299 (0.421, 12.553) 0.3242	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 16 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB I								N.M.E.
>= 12.3 MUT/MB	20	2 (10.0)	N.M.E.	24	0	N.M.E.	N.M.E.	
< 12.3 MUT/MB	26	4 (15.4)	N.M.E.	22	2 (9.1)	N.M.E.	N.M.E.	
NOT EVALUABLE/NOT REPORTED	42	6 (14.3)	N.M.E.	43	2 (4.7)	N.M.E.	N.M.E.	
TUMOR TISSUE TMB II								N.M.E.
OVERALL EVALUABLE	46	6 (13.0)	N.M.E.	46	2 (4.3)	N.M.E.	N.M.E.	
NOT EVALUABLE/NOT REPORTED	42	6 (14.3)	N.M.E.	43	2 (4.7)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 17 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.9923
CISPLATIN	61	10 (16.4)	N.A.	66	4 (6.1)	N.A.	2.886 (0.905, 9.206) 0.0603	
CARBOPLATIN	21	2 (9.5)	N.A.	19	0	N.E.	N.E. 0.1863	
TYPE OF PLATINUM THERAPY II								0.9924
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	10 (15.2)	N.A.	70	4 (5.7)	N.A.	2.814 (0.882, 8.975) 0.0673	
CARBOPLATIN	21	2 (9.5)	N.A.	19	0	N.E.	N.E. 0.1863	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Protocol: CA209816 Page 18 of 18

Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	12 (13.6)	N.A.	65	4 (6.2)	N.A.	2.329 (0.751, 7.225) 0.1313	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	0	N.E.	N.E. N.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:06

Anhang 4-G 5.3.3.2: Subgruppenanalysen für Endpunkt schwere UE auf SOC/PT-Ebene aus CA209-816 (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	11 (12.5)	N.A.	89	27 (30.3)	N.A.	0.376 (0.186, 0.758) 0.0044	
AGE CATEGORIZATION I								0.2664
< 65	47	6 (12.8)	N.A.	42	9 (21.4)	N.A.	0.599 (0.213, 1.684) 0.3239	
>= 65	41	5 (12.2)	N.A.	47	18 (38.3)	N.A. (3.29, N.A.)	0.267 (0.099, 0.719) 0.0051	
AGE CATEGORIZATION II								0.2211
< 65	47	6 (12.8)	N.A.	42	9 (21.4)	N.A.	0.599 (0.213, 1.684) 0.3239	
>= 65 AND < 75	36	4 (11.1)	N.A.	43	17 (39.5)	N.A. (2.43, N.A.)	0.236 (0.079, 0.702) 0.0047	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 2 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.9885
MALE	67	11 (16.4)	N.A.	65	25 (38.5)	N.A. (4.50, N.A.)	0.380 (0.187, 0.772) 0.0054	
FEMALE	21	0	N.E.	24	2 (8.3)	N.A.	N.E. 0.1812	
SEX (CRF)								0.9883
MALE	66	11 (16.7)	N.A.	65	25 (38.5)	N.A. (4.50, N.A.)	0.386 (0.190, 0.785) 0.0063	
FEMALE	22	0	N.E.	24	2 (8.3)	N.A.	N.E. 0.1711	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 3 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.2581
WHITE	37	2 (5.4)	N.A.	36	9 (25.0)	N.A.	0.197 (0.043, 0.915) 0.0212	
ASIAN	50	9 (18.0)	N.A.	52	17 (32.7)	N.A.	0.514 (0.229, 1.154) 0.0995	
REGION								0.3930
NORTH AMERICA	16	0	N.E.	21	2 (9.5)	N.A.	N.E. 0.2114	
EUROPE	18	2 (11.1)	N.A.	11	6 (54.5)	2.00 (0.72, N.A.)	0.162 (0.032, 0.808) 0.0117	
ASIA	50	9 (18.0)	N.A.	52	17 (32.7)	N.A.	0.514 (0.229, 1.154) 0.0995	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 4 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.0850
0	66	10 (15.2)	N.A. (2.83, N.A.)	63	16 (25.4)	N.A. (1.64, N.A.)	0.577 (0.262, 1.272) 0.1666	
>= 1	22	1 (4.5)	N.A.	26	11 (42.3)	N.A.	0.086 (0.011, 0.668) 0.0030	
TOBACCO USE								0.5827
NEVER SMOKED	9	1 (11.1)	N.A.	8	1 (12.5)	N.A.	0.831 (0.052, 13.314) 0.8961	
CURRENT/FORMER	79	10 (12.7)	N.A.	80	25 (31.3)	N.A.	0.371 (0.178, 0.773) 0.0058	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 5 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.7409
STAGE IB/II	36	5 (13.9)	N.A. (2.79, N.A.)	34	13 (38.2)	N.A.	0.328 (0.117, 0.921) 0.0257	
STAGE IIIA	52	6 (11.5)	N.A.	55	14 (25.5)	N.A.	0.417 (0.160, 1.085) 0.0643	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.5751
STAGE IB/II	32	5 (15.6)	N.A. (5.32, N.A.)	32	10 (31.3)	N.A.	0.475 (0.162, 1.391) 0.1644	
STAGE IIIA	56	6 (10.7)	N.A.	56	17 (30.4)	N.A.	0.315 (0.124, 0.799) 0.0102	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 6 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.0544
SQUAMOUS CELL CARCINOMA	47	10 (21.3)	N.A.	50	16 (32.0)	N.A.	0.639 (0.290, 1.408) 0.2595	
NON-SQUAMOUS	41	1 (2.4)	N.A.	39	11 (28.2)	N.A.	0.075 (0.010, 0.585) 0.0013	
PD-L1 STATUS (CLINICAL DATABASE) I								0.7102
1-49%	50	6 (12.0)	N.A.	47	15 (31.9)	N.A.	0.331 (0.128, 0.855) 0.0162	
>= 50%	38	5 (13.2)	N.A.	42	12 (28.6)	N.A.	0.428 (0.151, 1.217) 0.0997	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 7 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB I								0.4591
>= 12.3 MUT/MB	20	4 (20.0)	N.A.	24	5 (20.8)	N.A.	0.982 (0.263, 3.657) 0.9770	
< 12.3 MUT/MB	26	0	N.E.	22	4 (18.2)	N.A.	N.E. 0.0243	
NOT EVALUABLE/NOT REPORTED	42	7 (16.7)	N.A.	43	18 (41.9)	N.A. (3.02, N.A.)	0.356 (0.148, 0.853) 0.0155	
TUMOR TISSUE TMB II								0.8491
OVERALL EVALUABLE	46	4 (8.7)	N.A.	46	9 (19.6)	N.A.	0.409 (0.126, 1.329) 0.1239	
NOT EVALUABLE/NOT REPORTED	42	7 (16.7)	N.A.	43	18 (41.9)	N.A. (3.02, N.A.)	0.356 (0.148, 0.853) 0.0155	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 8 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.1917
CISPLATIN	61	4 (6.6)	N.A.	66	17 (25.8)	N.A.	0.232 (0.078, 0.689) 0.0041	
CARBOPLATIN	21	6 (28.6)	N.A. (4.47, N.A.)	19	8 (42.1)	N.A. (1.12, N.A.)	0.625 (0.216, 1.803) 0.3819	
TYPE OF PLATINUM THERAPY II								0.2081
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	5 (7.6)	N.A.	70	19 (27.1)	N.A.	0.253 (0.094, 0.678) 0.0031	
CARBOPLATIN	21	6 (28.6)	N.A. (4.47, N.A.)	19	8 (42.1)	N.A. (1.12, N.A.)	0.625 (0.216, 1.803) 0.3819	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 9 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	11 (12.5)	N.A.	65	18 (27.7)	N.A.	0.418 (0.197, 0.886) 0.0187	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	9 (37.5)	N.A. (1.28, N.A.)	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 10 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	6 (6.8)	N.A.	89	15 (16.9)	N.A.	0.384 (0.149, 0.991) 0.0397	
AGE CATEGORIZATION I								0.0736
< 65	47	5 (10.6)	N.A.	42	5 (11.9)	N.A.	0.911 (0.264, 3.148) 0.8835	
>= 65	41	1 (2.4)	N.A.	47	10 (21.3)	N.A.	0.101 (0.013, 0.793) 0.0072	
AGE CATEGORIZATION II								0.0968
< 65	47	5 (10.6)	N.A.	42	5 (11.9)	N.A.	0.911 (0.264, 3.148) 0.8835	
>= 65 AND < 75	36	1 (2.8)	N.A.	43	9 (20.9)	N.A.	0.118 (0.015, 0.931) 0.0148	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 11 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								0.9917
MALE	67	6 (9.0)	N.A.	65	14 (21.5)	N.A.	0.391 (0.150, 1.018) 0.0456	
FEMALE	21	0	N.E.	24	1 (4.2)	N.A.	N.E. 0.3496	
SEX (CRF)								0.9915
MALE	66	6 (9.1)	N.A.	65	14 (21.5)	N.A.	0.397 (0.153, 1.035) 0.0498	
FEMALE	22	0	N.E.	24	1 (4.2)	N.A.	N.E. 0.3384	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 12 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

	Arm C: Nivo + Chemo			Arm B: Chemo (Concurrent)			Arm C vs. Concurrent Arm B	
Adverse Events with CTCAE Grade 3-4-5 Subgroups	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								0.4251
WHITE	37	1 (2.7)	N.A.	36	5 (13.9)	N.A.	0.183 (0.021, 1.570) 0.0821	
ASIAN	50	5 (10.0)	N.A.	52	10 (19.2)	N.A.	0.492 (0.168, 1.440) 0.1858	
REGION								0.5810
NORTH AMERICA	16	0	N.E.	21	0	N.E.	N.E. N.E.	
EUROPE	18	1 (5.6)	N.A.	11	4 (36.4)	N.A. (0.92, N.A.)	0.129 (0.014, 1.154) 0.0303	
ASIA	50	5 (10.0)	N.A.	52	10 (19.2)	N.A.	0.492 (0.168, 1.440) 0.1858	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 13 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								0.9899
0	66	6 (9.1)	N.A.	63	11 (17.5)	N.A.	0.504 (0.186, 1.364) 0.1688	
>= 1	22	0	N.E.	26	4 (15.4)	N.A.	N.E. 0.0579	
TOBACCO USE								0.9904
NEVER SMOKED	9	0	N.E.	8	1 (12.5)	N.A. (0.56, N.A.)	N.E. 0.2888	
CURRENT/FORMER	79	6 (7.6)	N.A.	80	13 (16.3)	N.A.	0.447 (0.170, 1.176) 0.0929	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 14 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								0.8703
STAGE IB/II	36	4 (11.1)	N.A.	34	9 (26.5)	N.A.	0.398 (0.122, 1.292) 0.1112	
STAGE IIIA	52	2 (3.8)	N.A.	55	6 (10.9)	N.A.	0.339 (0.068, 1.679) 0.1637	
DISEASE STAGE AT STUDY ENTRY (CRF)								0.3986
STAGE IB/II	32	4 (12.5)	N.A.	32	7 (21.9)	N.A.	0.555 (0.163, 1.897) 0.3403	
STAGE IIIA	56	2 (3.6)	N.A.	56	8 (14.3)	N.A.	0.237 (0.050, 1.114) 0.0468	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 15 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								0.3828
SQUAMOUS CELL CARCINOMA	47	5 (10.6)	N.A.	50	10 (20.0)	N.A.	0.512 (0.175, 1.499) 0.2124	
NON-SQUAMOUS	41	1 (2.4)	N.A.	39	5 (12.8)	N.A.	0.179 (0.021, 1.536) 0.0773	
PD-L1 STATUS (CLINICAL DATABASE) I								0.1126
1-49%	50	2 (4.0)	N.A.	47	10 (21.3)	N.A.	0.171 (0.038, 0.782) 0.0096	
>= 50%	38	4 (10.5)	N.A.	42	5 (11.9)	N.A.	0.854 (0.229, 3.183) 0.8132	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 16 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	 Subjects with Event n (%)	 KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	 Subjects with Event n (%)	 KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB I								0.3741
>= 12.3 MUT/MB	20	3 (15.0)	N.A.	24	3 (12.5)	N.A.	1.251 (0.252, 6.205) 0.7832	
< 12.3 MUT/MB	26	0	N.E.	22	2 (9.1)	N.A.	N.E. 0.1198	
NOT EVALUABLE/NOT REPORTED	42	3 (7.1)	N.A.	43	10 (23.3)	N.A.	0.289 (0.080, 1.050) 0.0444	
TUMOR TISSUE TMB II								0.4610
OVERALL EVALUABLE	46	3 (6.5)	N.A.	46	5 (10.9)	N.A.	0.576 (0.137, 2.410) 0.4427	
NOT EVALUABLE/NOT REPORTED	42	3 (7.1)	N.A.	43	10 (23.3)	N.A.	0.289 (0.080, 1.050) 0.0444	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 17 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	 Subjects with Event n (%)	 KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	 Subjects with Event n (%)	 KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY I								0.2222
CISPLATIN	61	3 (4.9)	N.A.	66	12 (18.2)	N.A.	0.249 (0.070, 0.884) 0.0198	
CARBOPLATIN	21	3 (14.3)	N.A.	19	3 (15.8)	N.A.	0.907 (0.183, 4.497) 0.9054	
TYPE OF PLATINUM THERAPY II								0.2159
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	3 (4.5)	N.A.	70	12 (17.1)	N.A.	0.245 (0.069, 0.869) 0.0181	
CARBOPLATIN	21	3 (14.3)	N.A.	19	3 (15.8)	N.A.	0.907 (0.183, 4.497) 0.9054	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 18 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.A.
AVAILABLE IN ARM C	88	6 (6.8)	N.A.	65	8 (12.3)	N.A.	0.532 (0.185, 1.534) 0.2348	
NOT AVAILABLE IN ARM C	0	0	N.E.	24	7 (29.2)	N.A. (1.68, N.A.)	N.E. N.A.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 19 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	88	2 (2.3)	N.A.	89	9 (10.1)	N.A.	0.216 (0.047, 1.002) 0.0313	
AGE CATEGORIZATION I								N.M.E.
< 65	47	1 (2.1)	N.M.E.	42	4 (9.5)	N.M.E.	N.M.E.	
>= 65	41	1 (2.4)	N.M.E.	47	5 (10.6)	N.M.E.	N.M.E.	
AGE CATEGORIZATION II								N.M.E.
< 65	47	1 (2.1)	N.M.E.	42	4 (9.5)	N.M.E.	N.M.E.	
>= 65 AND < 75	36	1 (2.8)	N.M.E.	43	5 (11.6)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 20 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX (IRT)								N.M.E.
MALE	67	1 (1.5)	N.M.E.	65	8 (12.3)	N.M.E.	N.M.E.	
FEMALE	21	1 (4.8)	N.M.E.	24	1 (4.2)	N.M.E.	N.M.E.	
SEX (CRF)								N.M.E.
MALE	66	1 (1.5)	N.M.E.	65	8 (12.3)	N.M.E.	N.M.E.	
FEMALE	22	1 (4.5)	N.M.E.	24	1 (4.2)	N.M.E.	N.M.E.	

ssss

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 21 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9933
WHITE	37	0	N.E.	36	1 (2.8)	N.A.	N.E. 0.3039	
ASIAN	50	2 (4.0)	N.A.	52	8 (15.4)	N.A.	0.247 (0.053, 1.166) 0.0559	
REGION								>0.9999
NORTH AMERICA	16	0	N.E.	21	1 (4.8)	N.A.	N.E. 0.3827	
EUROPE	18	0	N.E.	11	0	N.E.	N.E. N.E.	
ASIA	50	2 (4.0)	N.A.	52	8 (15.4)	N.A.	0.247 (0.053, 1.166) 0.0559	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 22 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
BASELINE ECOG PS								N.M.E.
0	66	2 (3.0)	N.M.E.	63	7 (11.1)	N.M.E.	N.M.E.	
>= 1	22	0	N.M.E.	26	2 (7.7)	N.M.E.	N.M.E.	
TOBACCO USE								0.9933
NEVER SMOKED	9	0	N.E.	8	1 (12.5)	N.A. (2.50, N.A.)	N.E. 0.2888	
CURRENT/FORMER	79	2 (2.5)	N.A.	80	8 (10.0)	N.A.	0.244 (0.052, 1.150) 0.0533	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 23 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY (IRT)								N.M.E.
STAGE IB/II	36	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	
STAGE IIIA	52	2 (3.8)	N.M.E.	55	5 (9.1)	N.M.E.	N.M.E.	
DISEASE STAGE AT STUDY ENTRY (CRF)								N.M.E.
STAGE IB/II	32	0	N.M.E.	32	2 (6.3)	N.M.E.	N.M.E.	
STAGE IIIA	56	2 (3.6)	N.M.E.	56	6 (10.7)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 24 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
CELL TYPE AT STUDY ENTRY								N.M.E.
SQUAMOUS CELL CARCINOMA	47	1 (2.1)	N.M.E.	50	6 (12.0)	N.M.E.	N.M.E.	
NON-SQUAMOUS	41	1 (2.4)	N.M.E.	39	3 (7.7)	N.M.E.	N.M.E.	
PD-L1 STATUS (CLINICAL DATABASE) I								N.M.E.
1-49%	50	0	N.M.E.	47	3 (6.4)	N.M.E.	N.M.E.	
>= 50%	38	2 (5.3)	N.M.E.	42	6 (14.3)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 25 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR TISSUE TMB I								N.M.E.
>= 12.3 MUT/MB	20	0	N.M.E.	24	2 (8.3)	N.M.E.	N.M.E.	
< 12.3 MUT/MB	26	0	N.M.E.	22	0	N.M.E.	N.M.E.	
NOT EVALUABLE/NOT REPORTED	42	2 (4.8)	N.M.E.	43	7 (16.3)	N.M.E.	N.M.E.	
TUMOR TISSUE TMB II								N.M.E.
OVERALL EVALUABLE	46	0	N.M.E.	46	2 (4.3)	N.M.E.	N.M.E.	
NOT EVALUABLE/NOT REPORTED	42	2 (4.8)	N.M.E.	43	7 (16.3)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 26 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF PLATINUM THERAPY I								N.M.E.
CISPLATIN	61	1 (1.6)	N.M.E.	66	7 (10.6)	N.M.E.	N.M.E.	
CARBOPLATIN	21	1 (4.8)	N.M.E.	19	2 (10.5)	N.M.E.	N.M.E.	
TYPE OF PLATINUM THERAPY II								N.M.E.
CISPLATIN OR SWITCHING FROM CISPLATIN TO CARBOPLATIN	66	1 (1.5)	N.M.E.	70	7 (10.0)	N.M.E.	N.M.E.	
CARBOPLATIN	21	1 (4.8)	N.M.E.	19	2 (10.5)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Protocol: CA209816 Page 27 of 27

Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C

SOC: Metabolism and Nutrition Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TYPE OF CHEMOTHERAPY REGIMEN IN ARM B								N.M.E.
AVAILABLE IN ARM C	88	2 (2.3)	N.M.E.	65	7 (10.8)	N.M.E.	N.M.E.	
NOT AVAILABLE IN ARM C	0	0	N.M.E.	24	2 (8.3)	N.M.E.	N.M.E.	

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:23

Anhang 4-G 5.3.3.3: Subgruppenanalysen für Endpunkt schwerwiegende UE auf SOC/PT-Ebene aus CA209-816 (PD-L1-positive Population)

Protocol: CA209816 Page 1 of 1

Serious Adverse Events Over the Entire Study Period: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects in Concurrently Randomized Arms B and C
With PD-L1 Expression Level >= 1%

Serious Adverse Events Subgroups	Arm C: Nivo + Chemo N	Arm C: Nivo + Chemo Subjects with Event n (%)	Arm C: Nivo + Chemo KME (95%CI)(mon) (1)	Arm B: Chemo (Concurrent) N	Arm B: Chemo (Concurrent) Subjects with Event n (%)	Arm B: Chemo (Concurrent) KME (95%CI)(mon) (1)	Arm C vs. Concurrent Arm B HR (95%CI) P-value (2)(3)	Arm C vs. Concurrent Arm B Test for Interaction P-value (4)(5)

NO DATA AVAILABLE FOR THIS REPORT

Oct 2022 DBL. Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
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 Arm C over Conc. Arm B.
(3) Unstratified 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).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr1525.sas 17MAR2023:19:02:32

Anhang 4-G 6: Kaplan-Meier-Kurven aus CA209-816

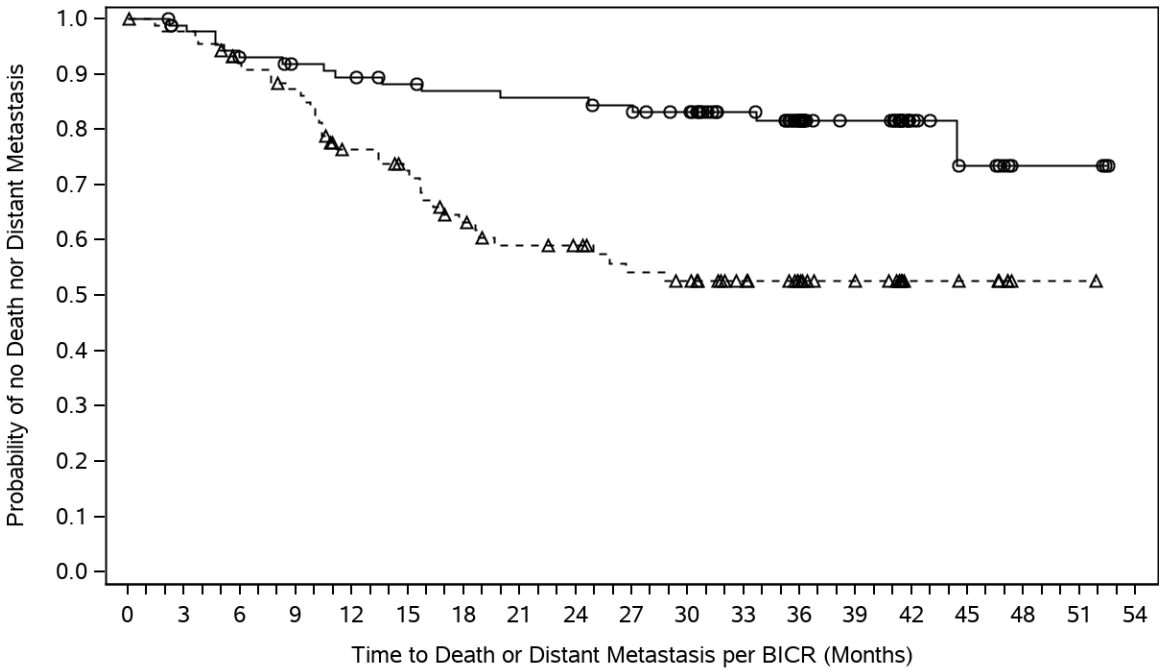
Anhang 4-G 6.1: Kaplan-Meier-Kurven für Endpunkte aus CA209-816 (PD-L1-positive Population)

Anhang 4-G 6.1.1: Kaplan-Meier-Kurven für Endpunkte Morbidität aus CA209-816 (PD-L1-positive Population)

Für die Zeit bis zum Tod oder dem Auftreten von Fernmetastasen (TTDM) sowie Gesundheitszustand gemäß EQ-5D-VAS (7 mm, 10 mm, 15 mm) – Zeit bis zur dauerhaften Verschlechterung (PD-L1-positive Population).

Protocol: CA209816 Page 1 of 1

Figure 13.3:
Time to Death or Distant Metastasis per BICR: Kaplan-Meier Plot - All Randomized Subjects in Concurrent Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

Arm C: Nivo + Chemo	89	85	79	76	74	71	69	68	68	66	62	52	42	28	13	8	3	3	0
Arm B: Chemo (Concurrent)	89	86	78	73	60	55	46	41	39	34	32	25	19	14	7	6	1	1	0

—o— Arm C: Nivo + Chemo (events: 16/89), median and 95% CI: N.A.

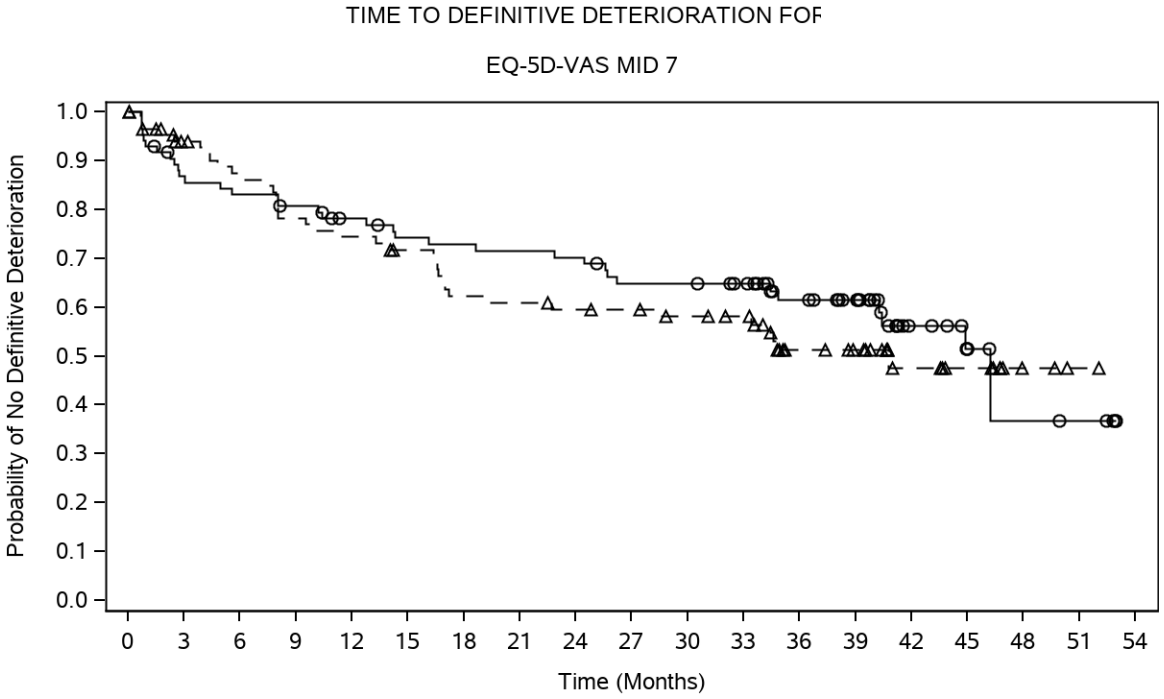
--△-- Arm B: Chemo (Concurrent) (events: 37/89), median and 95% CI: N.A. (18.83, N.A.)

Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 0.332 (0.183, 0.600), p-value: 0.0001

Oct 2022 DBL. Symbols represent censored observations.
Stratified Cox proportional hazard model and log-rank test
Stratified by disease stage (IB/II vs IIIA), sex (male vs female) per IRT
N.A: Not Available
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ef-osr1-ebr1525.sas 21MAR2023:15:34:56

Protocol: CA209816 Page 1 of 3

Figure 24.2:
EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Kaplan-Meier Plot - All Randomized Subjects in Concurrent Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

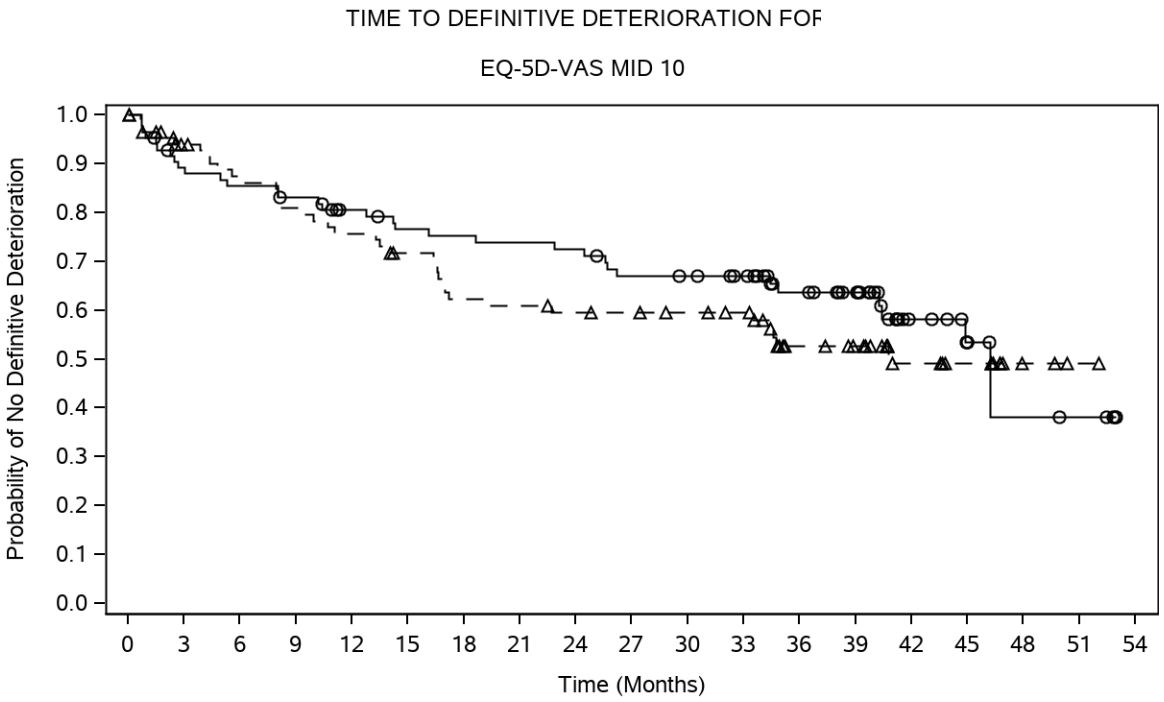
Arm C: Nivo + Chemo	84	71	68	65	60	56	55	54	53	48	48	45	36	31	15	9	5	4	0
Arm B: Chemo (Concurrent)	86	73	67	60	57	53	46	45	43	42	39	37	25	22	12	9	3	1	0

Arm C: Nivo + Chemo (events: 35/84), median and 95% CI: 46.23 (34.86, N.A.)
Arm B: Chemo (Concurrent) (events: 37/86), median and 95% CI: 40.77 (19.02, N.A.)
Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 0.780 (0.487, 1.247),
p-value: 0.2989

Oct 2022 DBL
Symbols represent censored observations.
Stratified Cox proportional hazard model.
Randomized subjects with non missing baseline assessment were included in this analysis.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-sy-eq5dr1-ebr1525.sas 16MAR2023:19:42:33

Protocol: CA209816 Page 2 of 3

Figure 24.2:
EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Kaplan-Meier Plot - All Randomized Subjects in Concurrent Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

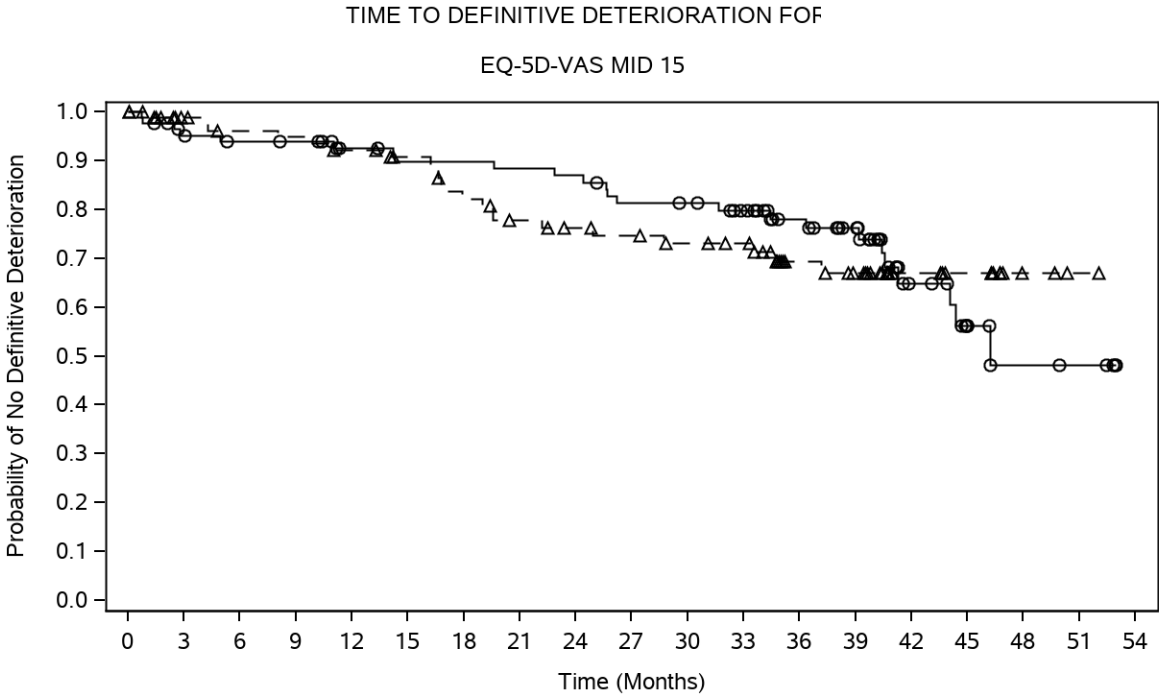
Arm C: Nivo + Chemo	84	73	70	67	61	57	56	55	54	49	48	45	36	31	15	9	5	4	0
Arm B: Chemo (Concurrent)	86	73	67	62	58	53	46	45	43	42	40	38	26	23	13	10	3	1	0

Arm C: Nivo + Chemo (events: 33/84), median and 95% CI: 46.23 (40.28, N.A.)
Arm B: Chemo (Concurrent) (events: 36/86), median and 95% CI: 40.77 (19.02, N.A.)
Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 0.759 (0.469, 1.228),
p-value: 0.2614

Oct 2022 DBL
Symbols represent censored observations.
Stratified Cox proportional hazard model.
Randomized subjects with non missing baseline assessment were included in this analysis.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-sy-eq5dr1-ebr1525.sas 16MAR2023:19:42:33

Protocol: CA209816 Page 3 of 3

Figure 24.2:
EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Kaplan-Meier Plot - All Randomized Subjects in Concurrent Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

Arm C: Nivo + Chemo

84 77 74 73 67 64 64 63 62 57 56 51 42 36 17 9 5 4 0

Arm B: Chemo (Concurrent)

86 76 72 71 68 64 57 52 49 47 44 42 30 26 13 10 3 1 0

Arm C: Nivo + Chemo (events: 24/84), median and 95% CI: 46.23 (41.30, N.A.)

Arm B: Chemo (Concurrent) (events: 22/86), median and 95% CI: N.A.

Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 0.790 (0.437, 1.426),
p-value: 0.4335

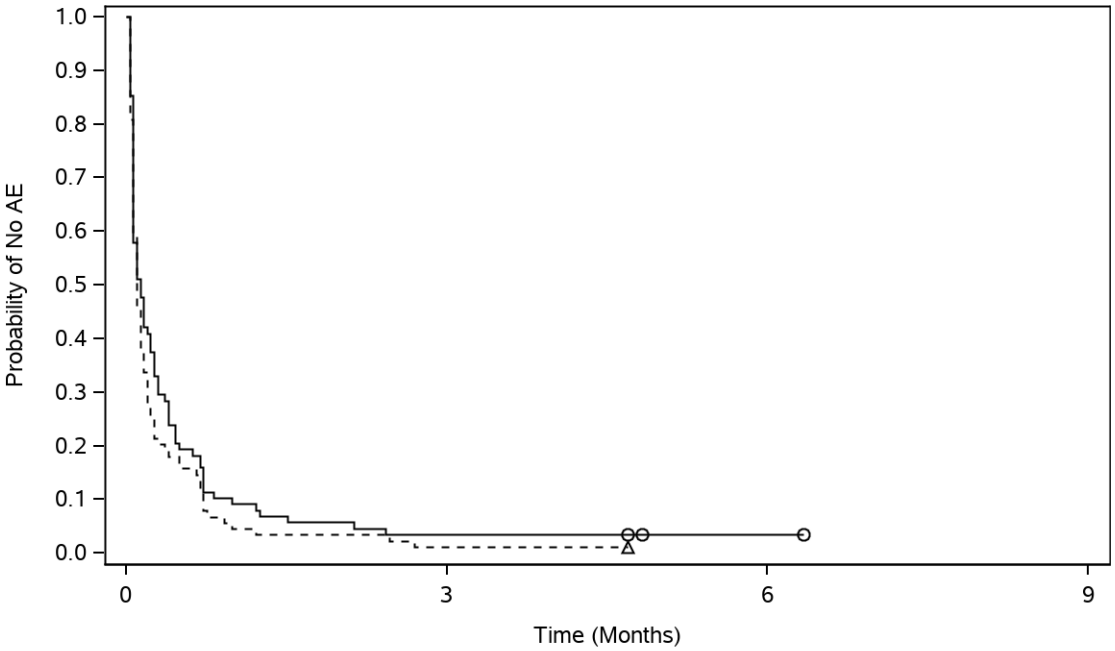
Oct 2022 DBL
Symbols represent censored observations.
Stratified Cox proportional hazard model.
Randomized subjects with non missing baseline assessment were included in this analysis.
MID = Minimal Important Difference
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-sy-eq5dr1-ebr1525.sas 16MAR2023:19:42:33

Anhang 4-G 6.1.2: Kaplan-Meier-Kurven für Endpunkte Verträglichkeit aus CA209-816 (PD-L1-positive Population)

Für die Endpunkte unerwünschte Ereignisse ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE im gesamten Beobachtungszeitraum: jegliche UE, schwere UE, schwerwiegende UE und zum Therapieabbruch führende UE (PD-L1-positive Population).

Protocol: CA209816 Page 1 of 1

Figure 29.1.1:
Any Adverse Events Over the Entire Study Period: Kaplan-Meier Plot - Excluding Progression Terms - All Treated Subjects in Concurrently Randomized Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

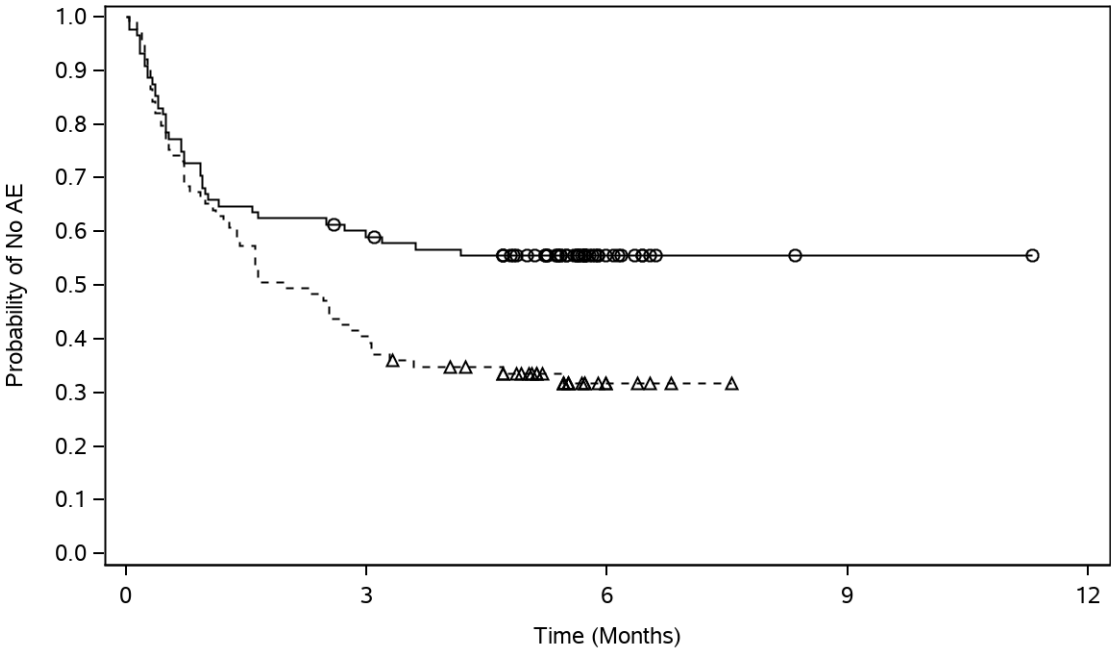
Arm C: Nivo + Chemo				
	88	3	1	0
Arm B: Chemo (Concurrent)				
	89	1	0	0

Arm C: Nivo + Chemo (events: 85/88), median and 95% CI: 0.13 (0.07, 0.23)
Arm B: Chemo (Concurrent) (events: 88/89), median and 95% CI: 0.10 (0.07, 0.13)
Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 0.832 (0.612, 1.132),
p-value: 0.2330

Oct 2022 DBL. Symbols represent censored observations.
Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant
systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
Stratified Cox proportional hazard model and stratified log-rank test.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ae-ebr1525b1.sas 16MAR2023:18:51:40

Protocol: CA209816 Page 1 of 1

Figure 29.1.2:
Any Adverse Events Over the Entire Study Period with CTCAE Grade 3-4-5: Kaplan-Meier Plot - Excluding Progression Terms - All Treated Subjects in Concurrently Randomized Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

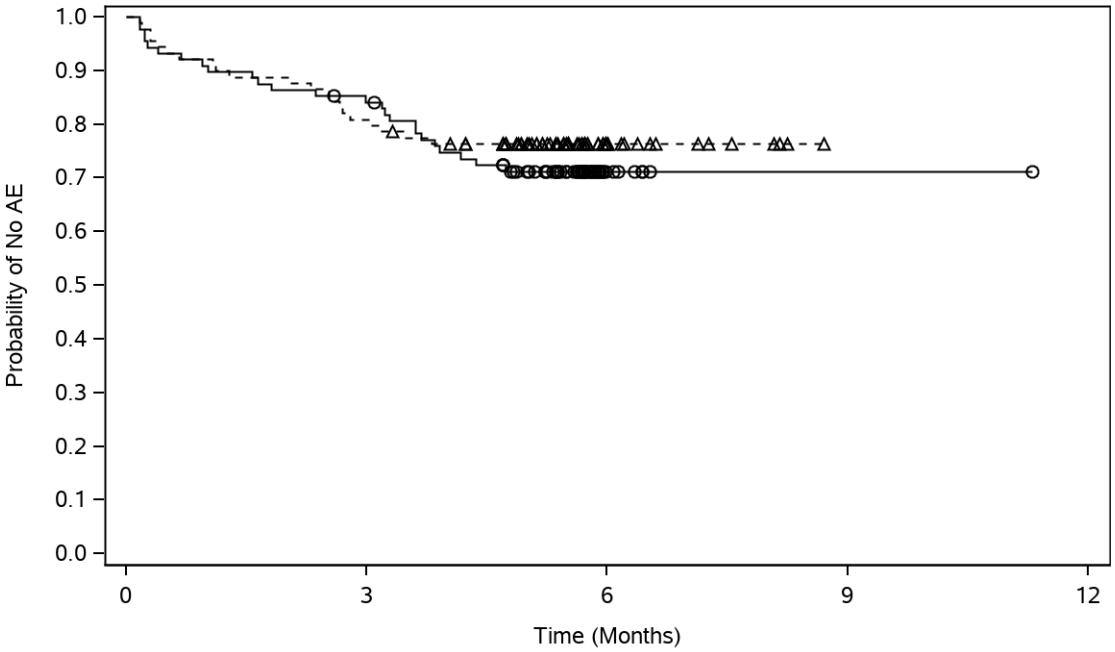
Arm C: Nivo + Chemo				
88	51	10	1	0
Arm B: Chemo (Concurrent)				
89	36	4	0	0

Arm C: Nivo + Chemo (events: 39/88), median and 95% CI: N.A. (2.73, N.A.)
Arm B: Chemo (Concurrent) (events: 60/89), median and 95% CI: 2.00 (1.28, 3.02)
Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 0.581 (0.387, 0.872),
p-value: 0.0078

Oct 2022 DBL. Symbols represent censored observations.
Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant
systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
Stratified Cox proportional hazard model and stratified log-rank test.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ae-ebr1525b1.sas 16MAR2023:18:52:17

Protocol: CA209816 Page 1 of 1

Figure 29.1.3:
Any Serious Adverse Events Over the Entire Study Period: Kaplan-Meier Plot - Excluding Progression Terms - All Treated Subjects in Concurrently Randomized Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

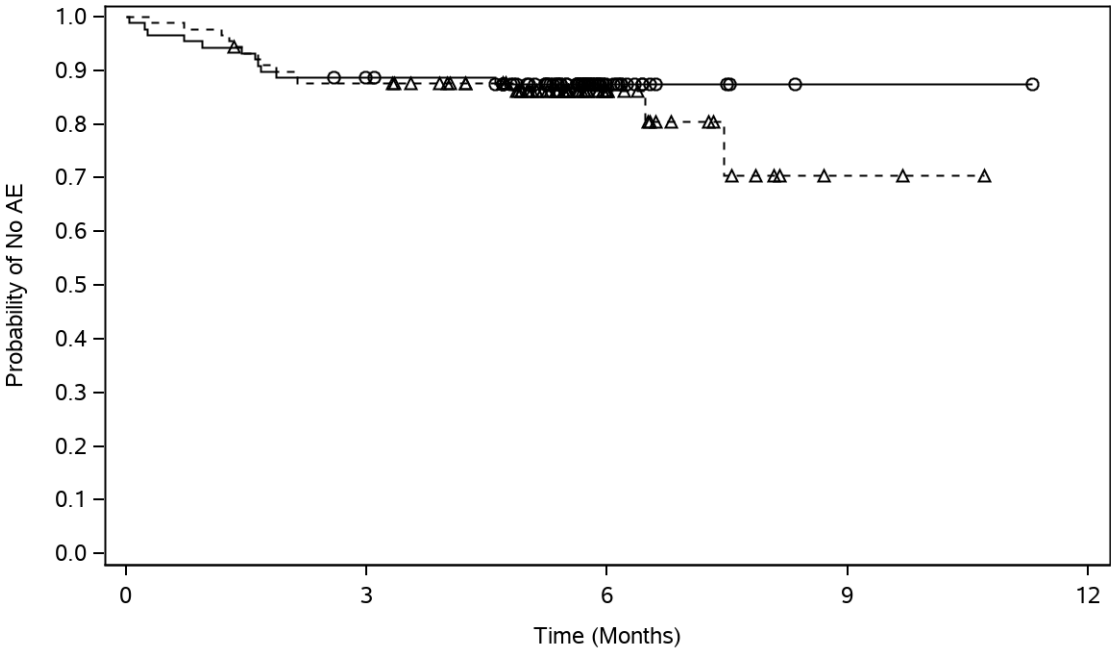
Arm C: Nivo + Chemo				
88	73	7	1	0
Arm B: Chemo (Concurrent)				
89	72	14	0	0

Arm C: Nivo + Chemo (events: 25/88), median and 95% CI: N.A.
Arm B: Chemo (Concurrent) (events: 21/89), median and 95% CI: N.A.
Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 1.191 (0.666, 2.131), p-value: 0.5561

Oct 2022 DBL. Symbols represent censored observations.
Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant
systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
Stratified Cox proportional hazard model and stratified log-rank test.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ae-ebr1525b1.sas 16MAR2023:18:52:53

Protocol: CA209816 Page 1 of 1

Figure 29.1.4:
Any Adverse Events Over the Entire Study Period Leading to Disc. of Study Treatment: Kaplan-Meier Plot - Excluding Progression Terms - All Treated Subjects in Concurrently Randomized Arms B and C - With PD-L1 Expression Level >= 1%



Number of Subjects at Risk

Arm C: Nivo + Chemo				
88	76	15	1	0
Arm B: Chemo (Concurrent)				
89	77	19	2	0

—o— Arm C: Nivo + Chemo (events: 11/88), median and 95% CI: N.A.

- -△- - Arm B: Chemo (Concurrent) (events: 14/89), median and 95% CI: N.A. (7.46, N.A.)

Hazard Ratio (Arm C: Nivo + Chemo vs. Arm B: Chemo (Conc.)) and 95% CI: 0.796 (0.358, 1.773), p-value: 0.5763

Oct 2022 DBL. Symbols represent censored observations.
Includes AEs reported between first dose and 100 days after last dose of neoadjuvant therapy, first dose adjuvant
systemic therapy and 30 days after its last dose and AEs identified as surgical complication up to 90 days after definitive surgery.
Stratified Cox proportional hazard model and stratified log-rank test.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ae-ebr1525b1.sas 16MAR2023:18:53:34

Anhang 4-G 7: Details zur Operationalisierung der Unerwünschten Ereignisse von besonderem Interesse (UESI)

Anhang 4-G 7.1: Definition von spezifischen immunvermittelten UE (imUE)

Protocol: CA209816 Page 1 of 4

Immune-Mediated Adverse Events Definition

Category	Preferred Terms
ADRENAL INSUFFICIENCY	Adrenal insufficiency
	Adrenocortical insufficiency acute
	Hypothalamic pituitary adrenal axis suppression
	Immune-mediated adrenal insuficiency
	Primary adrenal insufficiency
	Secondary adrenocortical insufficiency
DIABETES MELLITUS	Diabetes mellitus
	Diabetic ketoacidosis
	Diabetic ketosis
	Fulminant type 1 diabetes mellitus
	Latent autoimmune diabetes in adults
	Type 1 diabetes mellitus
DIARRHEA/COLITIS	Autoimmune colitis
	Autoimmune enteropathy
	Colitis
	Colitis ulcerative
	Diarrhoea
	Enteritis
	Enterocolitis
	Enterocolitis haemorrhagic
	Immune-mediated enterocolitis
	Immune-mediated gastritis
HEPATITIS	Acute hepatic failure
	Acute on chronic liver failure
	Alanine aminotransferase increased
	Aspartate aminotransferase increased
	Autoimmune cholangitis
	Autoimmune hepatitis
	Biliary cirrhosis
	Blood bilirubin increased
	Cholangitis
	Drug-induced liver injury
	Hepatic failure

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:36

Protocol: CA209816 Page 2 of 4

Immune-Mediated Adverse Events Definition

Category	Preferred Terms
HEPATITIS	Hepatitis Hepatitis acute Hepatotoxicity Hyperbilirubinaemia Immune-mediated cholangitis Immune-mediated cholestasis Immune-mediated hepatic disorder Immune-mediated hepatitis Transaminases increased
HYPERSENSITIVITY	Anaphylactic reaction Anaphylactic shock Hypersensitivity Infusion related hypersensitivity reaction Infusion related reaction
HYPERTHYROIDISM	Basedow's disease Hyperthyroidism Immune-mediated hyperthyroidism Primary hyperthyroidism
HYPOPHYSITIS	Hypophysitis Hypopituitarism Immune-mediated hypophysitis Lymphocytic hypophysitis
HYPOTHYROIDISM	Autoimmune hypothyroidism Hypothyroidism Immune-mediated hypothyroidism Primary hypothyroidism
HYPOTHYROIDISM/THYROIDITIS	Atrophic thyroiditis Autoimmune hypothyroidism Autoimmune thyroiditis Hypothyroidism Immune-mediated hypothyroidism

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:36

Protocol: CA209816 Page 3 of 4

Immune-Mediated Adverse Events Definition

Category	Preferred Terms
HYPOTHYROIDISM/THYROIDITIS	Immune-mediated thyroiditis Primary hypothyroidism Silent thyroiditis Thyroiditis Thyroiditis acute
NEPHRITIS AND RENAL DYSFUNCTION	Acute kidney injury Autoimmune nephritis Blood creatinine increased Creatinine renal clearance decreased End stage renal disease Glomerulonephritis rapidly progressive Hypercreatininaemia Immune-mediated nephritis Immune-mediated renal disorder Nephritis Nephritis allergic Paraneoplastic glomerulonephritis Renal failure Renal tubular necrosis Subacute kidney injury Tubulointerstitial nephritis
PNEUMONITIS	Hypersensitivity pneumonitis Idiopathic interstitial pneumonia Immune-mediated lung disease Interstitial lung disease Pneumonitis
RASH	Autoimmune blistering disease Autoimmune dermatitis Bullous haemorrhagic dermatosis Dermatitis Dermatitis acneiform Dermatitis allergic Dermatitis atopic

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:36

Protocol: CA209816 Page 4 of 4

Immune-Mediated Adverse Events Definition

Category	Preferred Terms
RASH	Dermatitis exfoliative
	Drug eruption
	Erythema multiforme
	Erythrodermic atopic dermatitis
	Exfoliative rash
	Fixed eruption
	Immune-mediated dermatitis
	Mucocutaneous disorder
	Mucosa vesicle
	Nodular rash
	Paradoxical psoriasis
	Pemphigoid
	Pemphigus
	Pustule
	Rash
	Rash erythematous
	Rash macular
	Rash maculo-papular
	Rash morbilliform
	Rash papular
	Rash pruritic
	Rash pustular
	Rash vesicular
	Scrotal dermatitis
	Stevens-Johnson syndrome
	Toxic epidermal necrolysis
	Toxic skin eruption
	Urticarial dermatitis
THYROIDITIS	Atrophic thyroiditis
	Autoimmune thyroiditis
	Immune-mediated thyroiditis
	Silent thyroiditis
	Thyroiditis
	Thyroiditis acute

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:36

Anhang 4-G 7.2: Definition von spezifischen UE (select UE)

Protocol: CA209816 Page 1 of 6

Select Adverse Events Definition

Category	Subcategory	Preferred Terms
ENDOCRINE ADVERSE EVENT	ADRENAL DISORDER	Adrenal insufficiency
		Adrenal suppression
		Adrenocortical insufficiency acute
		Blood corticotrophin decreased
		Blood corticotrophin increased
		Hypothalamic pituitary adrenal axis suppression
		Immune-mediated adrenal insuficiency
		Primary adrenal insufficiency
		Secondary adrenocortical insufficiency
	DIABETES	Diabetes mellitus
		Diabetic ketoacidosis
		Diabetic ketosis
		Fulminant type 1 diabetes mellitus
		Latent autoimmune diabetes in adults
		Type 1 diabetes mellitus
	PITUITARY DISORDER	Hypogonadism
		Hypophysitis
		Hypopituitarism
		Immune-mediated hypophysitis
		Lymphocytic hypophysitis
	THYROID DISORDER	Atrophic thyroiditis
		Autoimmune hypothyroidism
		Autoimmune thyroid disorder
		Autoimmune thyroiditis
		Basedow's disease
		Blood thyroid stimulating hormone decreased
		Blood thyroid stimulating hormone increased
		Hyperthyroidism
		Hypoparathyroidism
		Hypothyroidism
		Immune-mediated hyperthyroidism
		Immune-mediated hypothyroidism
		Immune-mediated thyroiditis

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:31

Protocol: CA209816 Page 2 of 6

Select Adverse Events Definition

Category	Subcategory	Preferred Terms
ENDOCRINE ADVERSE EVENT	THYROID DISORDER	Primary hyperthyroidism
		Primary hypothyroidism
		Silent thyroiditis
		Thyroid function test abnormal
		Thyroid hormones decreased
		Thyroid hormones increased
		Thyroiditis
		Thyroiditis acute
		Thyroxine decreased
		Thyroxine free decreased
		Thyroxine free increased
		Thyroxine increased
		Tri-iodothyronine uptake increased
GASTROINTESTINAL ADVERSE EVENT		Autoimmune colitis
		Autoimmune enteropathy
		Colitis
		Colitis ulcerative
		Diarrhoea
		Duodenal perforation
		Enteritis
		Enterocolitis
		Enterocolitis haemorrhagic
		Frequent bowel movements
		Gastrointestinal perforation
		Immune-mediated enterocolitis
		Immune-mediated gastritis
		Lower gastrointestinal perforation
		Ulcerative duodenitis
		Upper gastrointestinal perforation
HEPATIC ADVERSE EVENT		Acute hepatic failure
		Acute on chronic liver failure
		Alanine aminotransferase increased
		Aspartate aminotransferase increased
		Autoimmune cholangitis

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:31

Protocol: CA209816 Page 3 of 6

Select Adverse Events Definition

Category	Subcategory	Preferred Terms
HEPATIC ADVERSE EVENT		Autoimmune hepatitis
		Biliary cirrhosis
		Bilirubin conjugated decreased
		Bilirubin conjugated increased
		Blood alkaline phosphatase increased
		Blood bilirubin increased
		Cholangitis
		Drug-induced liver injury
		Gamma-glutamyltransferase increased
		Hepatic cytolysis
		Hepatic enzyme increased
		Hepatic failure
		Hepatitis
		Hepatitis acute
		Hepatotoxicity
		Hyperbilirubinaemia
		Immune-mediated cholangitis
		Immune-mediated cholestasis
		Immune-mediated hepatic disorder
		Immune-mediated hepatitis
		Liver disorder
		Liver function test abnormal
		Liver function test increased
		Liver injury
		Transaminases increased
HYPERSENSITIVITY/INFUSION REACTION		Anaphylactic reaction
		Anaphylactic shock
		Bronchospasm
		Hypersensitivity
		Infusion related hypersensitivity reaction
		Infusion related reaction
PULMONARY ADVERSE EVENT		Acute respiratory distress syndrome
		Acute respiratory failure
		Autoimmune lung disease

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:31

Protocol: CA209816 Page 4 of 6

Select Adverse Events Definition

Category	Subcategory	Preferred Terms
PULMONARY ADVERSE EVENT		Hypersensitivity pneumonitis
		Idiopathic interstitial pneumonia
		Immune-mediated lung disease
		Interstitial lung disease
		Lung infiltration
		Pneumonitis
RENAL ADVERSE EVENT		Acute kidney injury
		Autoimmune nephritis
		Blood creatinine increased
		Blood urea increased
		Creatinine renal clearance decreased
		End stage renal disease
		Glomerulonephritis rapidly progressive
		Hypercreatininaemia
		Immune-mediated nephritis
		Immune-mediated renal disorder
		Nephritis
		Nephritis allergic
		Paraneoplastic glomerulonephritis
		Renal failure
		Renal tubular necrosis
		Subacute kidney injury
		Tubulointerstitial nephritis
		Urine output decreased
SKIN ADVERSE EVENT		Anal eczema
		Anal rash
		Autoimmune blistering disease
		Autoimmune dermatitis
		Blister
		Bullous haemorrhagic dermatosis
		Dermatitis
		Dermatitis acneiform
		Dermatitis allergic
		Dermatitis atopic

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:31

Protocol: CA209816 Page 5 of 6

Select Adverse Events Definition

Category	Subcategory	Preferred Terms
SKIN ADVERSE EVENT		Dermatitis exfoliative
		Drug eruption
		Eczema
		Enanthema
		Erythema
		Erythema multiforme
		Erythrodermic atopic dermatitis
		Exfoliative rash
		Fixed eruption
		Generalised bullous fixed drug eruption
		Guttate psoriasis
		Immune-mediated dermatitis
		Mucocutaneous disorder
		Mucosa vesicle
		Nodular rash
		Palmar-plantar erythrodysaesthesia syndrome
		Paradoxical psoriasis
		Pemphigoid
		Pemphigus
		Photosensitivity reaction
		Pruritus
		Pruritus allergic
		Psoriasis
		Pustular psoriasis
		Pustule
		Rash
		Rash erythematous
		Rash macular
		Rash maculo-papular
		Rash morbilliform
		Rash papular
		Rash pruritic
		Rash pustular
		Rash vesicular
		SJS-TEN overlap
		Scrotal dermatitis

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:31

Protocol: CA209816 Page 6 of 6

Select Adverse Events Definition

Category	Subcategory	Preferred Terms
SKIN ADVERSE EVENT		Skin exfoliation
		Skin hypopigmentation
		Skin irritation
		Stevens-Johnson syndrome
		Toxic epidermal necrolysis
		Toxic skin eruption
		Urticaria
		Urticarial dermatitis
		Vitiligo
		Vulval eczema

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:31

Anhang 4-G 7.3: Definition von weiteren UE von speziellem Interesse (OESI)

Protocol: CA209816 Page 1 of 3

Other Events of Special Interest Definition

Category	Preferred Terms
DEMYELINATION EVENT	Anti-myelin-associated glycoprotein associated polyneuropathy
	Demyelinating polyneuropathy
	Demyelination
ENCEPHALITIS EVENT	Acute disseminated encephalomyelitis
	Acute encephalitis with refractory, repetitive partial seizures
	Autoimmune encephalopathy
	Bickerstaff's encephalitis
	Encephalitis
	Encephalitis allergic
	Encephalitis autoimmune
	Encephalitis brain stem
	Encephalitis haemorrhagic
	Encephalitis lethargica
	Encephalitis toxic
	Immune effector cell-associated neurotoxicity syndrome
	Immune-mediated encephalitis
	Immune-mediated encephalopathy
	Limbic encephalitis
	Lupus encephalitis
	Noninfective encephalitis
	Panencephalitis
	Rasmussen encephalitis
	Subacute sclerosing panencephalitis
GRAFT VERSUS HOST DISEASE	Acute graft versus host disease
	Acute graft versus host disease in intestine
	Acute graft versus host disease in liver
	Acute graft versus host disease in skin
	Acute graft versus host disease oral
	Chronic graft versus host disease
	Chronic graft versus host disease in eye
	Chronic graft versus host disease in intestine
	Chronic graft versus host disease in liver
	Chronic graft versus host disease in skin
	Chronic graft versus host disease oral

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:42

Protocol: CA209816 Page 2 of 3

Other Events of Special Interest Definition

Category	Preferred Terms
GRAFT VERSUS HOST DISEASE	Graft versus host disease Graft versus host disease in eye Graft versus host disease in gastrointestinal tract Graft versus host disease in liver Graft versus host disease in lung Graft versus host disease in skin
GUILLAIN-BARRE SYNDROME	Guillain-Barre syndrome Miller Fisher syndrome
MYASTHENIC SYNDROME	Myasthenia gravis Myasthenia gravis crisis Myasthenic syndrome Ocular myasthenia
MYOCARDITIS EVENT	Autoimmune myocarditis Eosinophilic myocarditis Giant cell myocarditis Hypersensitivity myocarditis Immune-mediated myocarditis Myocarditis
MYOSITIS/RHABDOMYOLYSIS EVENT	Autoimmune myositis Dermatomyositis Immune-mediated myositis Inclusion body myositis Myositis Necrotising myositis Paraneoplastic dermatomyositis Polymyositis Rhabdomyolysis
PANCREATITIS EVENT	Autoimmune pancreatitis Haemorrhagic necrotic pancreatitis Immune-mediated pancreatitis Pancreatitis

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:42

Protocol: CA209816 Page 3 of 3

Other Events of Special Interest Definition

Category	Preferred Terms
PANCREATITIS EVENT	Pancreatitis acute
	Pancreatitis necrotising
	Subacute pancreatitis
UVEITIS EVENT	Autoimmune uveitis
	Chorioretinitis
	Cyclitis
	Immune recovery uveitis
	Immune-mediated uveitis
	Iridocyclitis
	Iritis
	Keratouveitis
	Uveitis
	Vogt-Koyanagi-Harada disease

MedDRA Version: 24.0
Program Source: /opt/zfs002/prd/bms246691/stats/primary/prog/listings/rl-ae-slaedef.sas 25NOV2021:15:25:42