Dossier zur Nutzenbewertung gemäß § 35a SGB V

Nivolumab (OPDIVO®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4T

Anhang 4-G

Nivolumab ist in Kombination mit Ipilimumab für die Erstlinienbehandlung des nicht resezierbaren fortgeschrittenen, rezidivierten oder metastasierten Plattenepithelkarzinoms des Ösophagus mit Tumorzell-PD-L1-Expression ≥ 1 % bei Erwachsenen indiziert.

Ergänzende Analysen

Stand: 29.04.2022

Anhang 4-G – Ergänzende Analysen aus CA209-648, 2. Datenschnitt vom 23. August 2021

Inhalt

Anhang 4-G – Ergänzende Analysen aus CA209-648, 2. Datenschnitt vom 23. August 2021 ... 1
1 Gesamtüberleben (ITT-Population der Patienten mit PD-L1 TC ≥ 1 %) ... 5
1.1 Subgruppenanalysen für den Endpunkt „Gesamtüberleben“ ... 6
2 Gesundheitszustand gemäß EQ-5D VAS (ITT-Population der Patienten mit PD-L1 TC ≥ 1 %) ... 17
2.1 KM-Kurven – MID = 7 ... 18
2.2 Zeit bis zur dauerhaften Verschlechterung (MID = 7, 10, 15) ... 19
2.3 Zusatzanalyse – Art der Ereignisse und Zensierungen für die Zeit bis zur dauerhaften Verschlechterung (MID = 7, 10, 15) ... 20
2.4 Subgruppenanalysen – MID = 7, 10, 15 ... 22
2.5 Zusatzanalyse – Mittlere Änderung während der Behandlung (MMRM) ... 61
2.6 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung im Behandlungsverlauf (MMRM) ... 62
3 Gesundheitsbezogene Lebensqualität gemäß FACT-E (ITT-Population der Patienten mit PD-L1 TC ≥ 1 %) ... 63
3.1 KM-Kurven – FACT-E Gesamtscore (MID = 27) ... 64
3.2 KM-Kurven – FACT-G Gesamtscore (MID = 3) ... 65
3.3 KM-Kurven – FACT-G Subskala PWB (MID = 3) ... 66
3.4 KM-Kurven – FACT-G Subskala SWB (MID = 3) ... 67
3.5 KM-Kurven – FACT-G Subskala EWB (MID = 3) ... 68
3.6 KM-Kurven – FACT-G Subskala FWB (MID = 3) ... 69
3.7 KM-Kurven – ECS (MID = 11) ... 70
3.8 KM-Kurven – FACT-G7 Gesamtscore (MID = 5) ... 71
3.9 Zeit bis zur dauerhaften Verschlechterung des FACT-G Gesamtscores (MID = 3, 7, 17) ... 72
3.10 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala PWB (MID = 2, 3, 5) ... 73
3.11 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala SWB (MID = 2, 3, 5) ... 74
3.12 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala EWB (MID = 2, 3, 4) ... 75
3.13 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala FWB (MID = 2, 3, 5) ... 76
3.14 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-E Gesamtscores (MID = 27) ... 77
3.15 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Gesamtscores (MID = 3, 7, 17) ... 78
3.16 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala PWB (MID = 2, 3, 5) ... 80
3.17 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala SWB (MID = 2, 3, 5) ... 82
3.18 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala EWB (MID = 2, 3, 4) ... 84

3.19 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala FWB (MID = 2, 3, 5) ... 86
3.20 Zusatzanalyse – Art der Ereignisse und Zensierungen – ECS (MID = 11) ... 88
3.21 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G7 Gesamtscores (MID = 5) ... 89
3.22 Subgruppenanalysen – FACT-E Gesamtscore (MID = 27) ... 90
3.23 Subgruppenanalysen – FACT-G Gesamtscore (MID = 3, 7, 17) ... 103
3.24 Subgruppenanalysen – FACT-G Subskala PWB (MID = 2, 3, 5) ... 142
3.25 Subgruppenanalysen – FACT-G Subskala SWB (MID = 2, 3, 5) ... 181
3.26 Subgruppenanalysen – FACT-G Subskala EWB (MID = 2, 3, 4) ... 220
3.27 Subgruppenanalysen – FACT-G Subskala FWB (MID = 2, 3, 5) ... 259
3.28 Subgruppenanalysen – ECS (MID = 11) ... 298
3.29 Subgruppenanalysen – FACT-G7 Gesamtscore (MID = 5) ... 311
3.30 Zusatzanalyse – Mittlere Änderung des FACT-E Gesamtscores während der Behandlung (MMRM) ... 324
3.31 Zusatzanalyse – Mittlere Änderung des FACT-G Gesamtscores während der Behandlung (MMRM) ... 325
3.32 Zusatzanalyse – Mittlere Änderung der Subskala PWB während der Behandlung (MMRM) ... 326
3.33 Zusatzanalyse – Mittlere Änderung der Subskala SWB während der Behandlung (MMRM) ... 327
3.34 Zusatzanalyse – Mittlere Änderung der Subskala EWB während der Behandlung (MMRM) ... 328
3.35 Zusatzanalyse – Mittlere Änderung der Subskala FWB während der Behandlung (MMRM) ... 329
3.36 Zusatzanalyse – Mittlere Änderung der ECS während der Behandlung (MMRM) ... 330
3.37 Zusatzanalyse – Mittlere Änderung des FACT-G7 Gesamtscores während der Behandlung (MMRM) ... 331
3.38 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung des FACT-E Gesamtscores im Behandlungsverlauf (MMRM) ... 332
3.39 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung des FACT-G Gesamtscore im Behandlungsverlauf (MMRM) ... 333
3.40 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala PWB im Behandlungsverlauf (MMRM) ... 334
3.41 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala SWB im Behandlungsverlauf (MMRM) ... 335
3.42 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala EWB im Behandlungsverlauf (MMRM) ... 336
3.43 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala FWB im Behandlungsverlauf (MMRM) ... 337
3.44 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der ECS im Behandlungsverlauf (MMRM) ... 338
3.45 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung des FACT-G7 Gesamtscores im Behandlungsverlauf (MMRM) ... 339
4 Verträglichkeit – Unerwünschte Ereignisse (Safety-Population der Patienten mit PD-L1 TC ≥ 1 %) ... 340
4.1 „Gesamtraten“ der Unerwünschten Ereignisse ... 340
4.1.1 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen UE ... 341
4.1.2 KM-Kurven – Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3) ... 342

4.1.3 KM-Kurven – Zeit bis zum ersten Auftreten von SUE ... 343
4.1.4 KM-Kurven – Zeit bis zum ersten Auftreten von zum Therapieabbruch führenden UE ... 344
4.1.5 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen UE ... 345
4.1.6 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3) ... 357
4.1.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von SUE ... 369
4.1.8 Subgruppenanalysen – Zeit bis zum ersten Auftreten von zum Therapieabbruch führenden UE ... 381
4.2 Zusatzanalysen Unerwünschte Ereignisse auf SOC/PT-Ebene ... 393
4.2.1 Zeit bis zum ersten Auftreten von jeglichen UE auf SOC/PT-Ebene ... 394
4.2.2 Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3) auf SOC/PT-Ebene ... 403
4.2.3 Zeit bis zum ersten Auftreten von SUE auf SOC/PT-Ebene ... 406
4.2.4 Zum Therapieabbruch führende UE auf SOC/PT-Ebene (deskriptive Analyse) 408
4.2.5 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen UE auf SOC/PT-Ebene ... 412
4.2.6 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3) auf SOC/PT-Ebene ... 893
4.2.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von SUE auf SOC/PT-Ebene ... 958
4.3 Zusatzanalysen Unerwünschte Ereignisse von besonderem Interesse (AESI) ... 984
4.3.1 Zusatzanalysen: Spezifische UE ... 984
4.3.1.1 Zeit bis zum ersten Auftreten von jeglichen spezifischen UE ... 985
4.3.1.2 Zeit bis zum ersten Auftreten von schweren spezifischen UE (CTCAE Grad ≥ 3) ... 986
4.3.1.3 Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen UE ... 987
4.3.1.4 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen spezifischen UE ... 988
4.3.1.5 KM-Kurven – Zeit bis zum ersten Auftreten von schweren spezifischen UE (CTCAE Grad ≥ 3) ... 989
4.3.1.6 KM-Kurven – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen UE ... 990
4.3.1.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen spezifischen UE ... 991
4.3.1.8 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren spezifischen UE (CTCAE Grad ≥ 3) ... 1004
4.3.1.9 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen UE ... 1017
4.3.2 Zusatzanalysen: Spezifische immunvermittelte UE (imUE) ... 1030
4.3.2.1 Zeit bis zum ersten Auftreten von jeglichen spezifischen imUE ... 1031
4.3.2.2 Zeit bis zum ersten Auftreten von schweren spezifischen imUE (CTCAE Grad ≥ 3) ... 1033
4.3.2.3 Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen imUE. 1035
4.3.2.4 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen spezifischen imUE ... 1037
4.3.2.5 KM-Kurven – Zeit bis zum ersten Auftreten von schweren spezifischen imUE (CTCAE Grad ≥ 3) ... 1038
4.3.2.6 KM-Kurven – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen imUE ... 1039

4.3.2.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen spezifischen imUE 1040
4.3.2.8 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren spezifischen imUE (CTCAE Grad ≥ 3) 1052
4.3.2.9 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen imUE 1064
4.3.3 Zusatzanalysen: Weitere UE von besonderem Interesse (OESI) 1074
4.3.3.1 Zeit bis zum ersten Auftreten von jeglichen OESI 1075
4.3.3.2 Zeit bis zum ersten Auftreten von schweren OESI (CTCAE Grad ≥ 3) 1077
4.3.3.3 Zeit bis zum ersten Auftreten von schwerwiegenden OESI 1079
4.3.3.4 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen OESI 1081
4.3.3.5 KM-Kurven – Zeit bis zum ersten Auftreten von schweren OESI (CTCAE Grad ≥ 3) 1082
4.3.3.6 KM-Kurven – Zeit bis zum ersten Auftreten von schwerwiegenden OESI 1083

1 Gesamtüberleben (ITT-Population der Patienten mit PD-L1 TC ≥ 1 %)

1.1 Subgruppenanalysen für den Endpunkt „Gesamtüberleben“

Protocol: CA209648 Page 1 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
OVERALL	158	119 (75.3)	13.70 (11.24, 17.41)	157	130 (82.8)	9.07 (7.69, 10.02)	0.641 (0.498, 0.826) 0.0005	
AGE								0.1318
< 65	95	74 (77.9)	12.88 (8.67, 15.51)	82	65 (79.3)	9.49 (7.43, 12.22)	0.783 (0.560, 1.095) 0.1521	
>= 65 AND < 75	55	41 (74.5)	14.62 (10.87, 23.36)	60	52 (86.7)	8.57 (7.36, 11.37)	0.536 (0.352, 0.817) 0.0033	
>= 75	8	4 (50.0)	27.10 (2.00, N.A.)	15	13 (86.7)	10.45 (5.75, 14.62)	0.271 (0.085, 0.862) 0.0192	
SEX								0.9087
MALE	131	100 (76.3)	13.86 (11.24, 17.81)	131	109 (83.2)	8.80 (7.52, 9.92)	0.641 (0.486, 0.845) 0.0015	
FEMALE	27	19 (70.4)	12.12 (8.71, 28.85)	26	21 (80.8)	13.11 (6.80, 18.86)	0.702 (0.375, 1.312) 0.2652	

Oct 2021 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).
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Protocol: CA209648 Page 2 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.8985
ASIAN	117	84 (71.8)	15.11 (11.27, 19.78)	113	88 (77.9)	9.92 (8.11, 12.19)	0.655 (0.484, 0.887) 0.0059	
NON-ASIAN	41	35 (85.4)	12.06 (6.57, 17.81)	44	42 (95.5)	7.61 (6.51, 9.49)	0.583 (0.364, 0.934) 0.0233	
REGION (PER CRF)								0.7107
J/K/T	91	62 (68.1)	18.30 (12.29, 24.08)	90	67 (74.4)	9.92 (8.57, 12.81)	0.625 (0.440, 0.888) 0.0082	
REST OF ASIA	25	21 (84.0)	8.67 (7.26, 13.70)	23	21 (91.3)	8.77 (3.88, 13.83)	0.848 (0.462, 1.557) 0.5923	
REST OF WORLD	42	36 (85.7)	12.09 (6.80, 17.81)	44	42 (95.5)	7.61 (6.51, 9.49)	0.565 (0.353, 0.903) 0.0158	

Oct 2021 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).
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Protocol: CA209648 Page 3 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
REGION								0.8281
ASIA	116	83 (71.6)	14.62 (11.27, 19.29)	113	88 (77.9)	9.92 (8.11, 12.19)	0.658 (0.486, 0.892) 0.0066	
NON-ASIA	42	36 (85.7)	12.09 (6.80, 17.81)	44	42 (95.5)	7.61 (6.51, 9.49)	0.565 (0.353, 0.903) 0.0158	
ECOG PS (PER CRF)								0.8567
0	71	50 (70.4)	18.30 (13.08, 24.08)	70	53 (75.7)	10.09 (7.82, 13.40)	0.638 (0.432, 0.942) 0.0229	
1	87	69 (79.3)	11.17 (7.59, 13.70)	85	75 (88.2)	8.11 (7.06, 9.49)	0.636 (0.454, 0.891) 0.0081	
WEIGHT								0.7207
< 60 KG	96	73 (76.0)	12.62 (8.74, 17.02)	83	68 (81.9)	9.07 (7.43, 10.09)	0.667 (0.476, 0.934) 0.0178	
>= 60 KG	62	46 (74.2)	14.42 (12.06, 23.43)	74	62 (83.8)	9.49 (7.46, 12.22)	0.606 (0.412, 0.891) 0.0103	

Oct 2021 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).
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Protocol: CA209648 Page 4 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8661
STAGE I	5	3 (60.0)	29.27 (12.12, N.A.)	5	3 (60.0)	17.77 (9.49, N.A.)	0.918 (0.185, 4.564) 0.9172	
STAGE II	5	4 (80.0)	9.72 (5.26, N.A.)	6	4 (66.7)	5.29 (0.72, N.A.)	0.544 (0.132, 2.244) 0.3932	
STAGE III	33	27 (81.8)	11.27 (7.98, 15.51)	49	44 (89.8)	9.40 (7.06, 13.11)	0.709 (0.436, 1.153) 0.1641	
STAGE IV	114	84 (73.7)	14.42 (11.24, 19.78)	97	79 (81.4)	8.80 (7.52, 9.92)	0.602 (0.439, 0.825) 0.0014	

Oct 2021 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).
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Protocol: CA209648 Page 5 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.7790
GX	11	7 (63.6)	11.24 (2.00, N.A.)	14	12 (85.7)	7.62 (5.62, 17.25)	0.809 (0.316, 2.073) 0.6585	
G1	8	7 (87.5)	12.57 (2.46, 33.48)	8	7 (87.5)	9.12 (4.76, 10.09)	0.552 (0.169, 1.800) 0.3181	
G2	58	44 (75.9)	12.52 (8.71, 23.36)	56	47 (83.9)	8.57 (6.51, 12.81)	0.579 (0.379, 0.884) 0.0104	
G3	28	24 (85.7)	15.36 (5.88, 23.43)	40	32 (80.0)	10.02 (8.61, 14.78)	0.839 (0.490, 1.436) 0.5233	
NOT OTHERWISE SPECIFIED	51	36 (70.6)	14.62 (10.28, 19.78)	39	32 (82.1)	7.82 (6.28, 12.09)	0.575 (0.354, 0.934) 0.0238	

Oct 2021 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).
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Protocol: CA209648 Page 6 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9040
UPPER THORACIC	37	26 (70.3)	17.02 (7.59, 23.36)	29	24 (82.8)	9.40 (7.06, 17.87)	0.765 (0.438, 1.337) 0.3455	
MIDDLE THORACIC	50	40 (80.0)	12.29 (8.74, 18.30)	58	48 (82.8)	8.57 (6.80, 9.95)	0.599 (0.389, 0.922) 0.0186	
LOWER THORACIC	59	42 (71.2)	14.00 (9.20, 26.78)	61	51 (83.6)	9.49 (7.06, 11.73)	0.615 (0.406, 0.933) 0.0212	
GASTROESOPHAGEAL JUNCTION	11	10 (90.9)	8.80 (3.02, 21.19)	9	7 (77.8)	9.63 (5.68, 12.81)	0.559 (0.192, 1.628) 0.2798	

Oct 2021 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).
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Protocol: CA209648 Page 7 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5923
RECURRENT - LOCO-REGIONAL	8	6 (75.0)	13.37 (4.44, N.A.)	14	9 (64.3)	14.75 (5.95, N.A.)	1.080 (0.379, 3.079) 0.8852	
RECURRENT - DISTANT	25	21 (84.0)	10.87 (3.91, 25.95)	27	25 (92.6)	9.49 (7.36, 12.81)	0.667 (0.366, 1.219) 0.1854	
DE NOVO METASTATIC	107	77 (72.0)	13.08 (9.20, 19.78)	89	73 (82.0)	8.61 (7.46, 9.63)	0.581 (0.418, 0.807) 0.0011	
UNRESECTABLE ADVANCED	18	15 (83.3)	19.75 (11.17, 25.99)	27	23 (85.2)	12.09 (5.29, 14.78)	0.601 (0.311, 1.162) 0.1266	
SMOKING STATUS								0.3626
CURRENT/FORMER	136	101 (74.3)	13.86 (12.09, 17.81)	119	98 (82.4)	8.84 (7.59, 9.76)	0.607 (0.458, 0.806) 0.0005	
NEVER/UNKNOWN	22	18 (81.8)	10.22 (6.80, 27.60)	38	32 (84.2)	9.95 (7.06, 13.83)	0.820 (0.457, 1.470) 0.5029	

Oct 2021 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-ossub-503.sas 02MAR2022:12:25:31

Protocol: CA209648 Page 8 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
ALCOHOL USE								0.9130
CURRENT/FORMER	126	95 (75.4)	13.04 (11.24, 17.61)	123	102 (82.9)	9.07 (7.72, 10.02)	0.651 (0.491, 0.865) 0.0028	
NEVER/UNKNOWN	32	24 (75.0)	15.41 (8.71, 19.98)	34	28 (82.4)	9.43 (6.11, 13.40)	0.626 (0.359, 1.091) 0.0967	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4569
<= 1	80	54 (67.5)	19.78 (12.88, 25.95)	79	62 (78.5)	9.49 (7.13, 12.22)	0.590 (0.408, 0.853) 0.0046	
>= 2	78	65 (83.3)	9.49 (7.59, 13.08)	78	68 (87.2)	8.61 (7.52, 9.92)	0.678 (0.476, 0.966) 0.0305	

Oct 2021 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-ossub-503.sas 02MAR2022:12:25:31

Protocol: CA209648 Page 9 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2850
< 1 YEAR	128	94 (73.4)	14.42 (11.27, 20.24)	126	106 (84.1)	8.84 (7.52, 9.95)	0.560 (0.421, 0.744) <0.0001	
1 - < 3 YEARS	25	21 (84.0)	9.72 (5.26, 15.11)	22	19 (86.4)	8.97 (5.95, 14.75)	0.866 (0.464, 1.617) 0.6522	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.1745
YES	38	32 (84.2)	11.88 (7.26, 17.41)	38	32 (84.2)	9.49 (7.36, 14.00)	0.855 (0.523, 1.399) 0.5324	
NO	120	87 (72.5)	14.00 (12.06, 19.78)	119	98 (82.4)	8.80 (7.49, 9.92)	0.583 (0.434, 0.784) 0.0003	

Oct 2021 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-ossub-503.sas 02MAR2022:12:25:31

Protocol: CA209648 Page 10 of 11

Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.5474
YES	26	22 (84.6)	12.11 (4.34, 16.43)	28	23 (82.1)	7.52 (5.95, 9.92)	0.781 (0.431, 1.417) 0.4153	
NO	132	97 (73.5)	13.86 (11.24, 19.29)	129	107 (82.9)	9.43 (7.82, 11.37)	0.615 (0.465, 0.813) 0.0006	
PD-L1 CPS I								0.8200
< 10	53	42 (79.2)	12.12 (7.59, 15.11)	54	52 (96.3)	9.07 (7.16, 9.95)	0.616 (0.407, 0.934) 0.0212	
>= 10	92	67 (72.8)	16.30 (11.27, 21.03)	100	77 (77.0)	8.97 (7.46, 12.09)	0.618 (0.443, 0.864) 0.0045	
PD-L1 CPS II								0.5676
< 5	29	25 (86.2)	8.48 (3.65, 13.08)	24	24 (100.0)	8.84 (6.11, 9.95)	0.740 (0.414, 1.324) 0.3076	
>= 5	116	84 (72.4)	15.11 (12.09, 20.24)	130	105 (80.8)	9.20 (7.52, 11.37)	0.586 (0.437, 0.784) 0.0003	

Oct 2021 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-ossub-503.sas 02MAR2022:12:25:31

Protocol: CA209648 Page 11 of 11

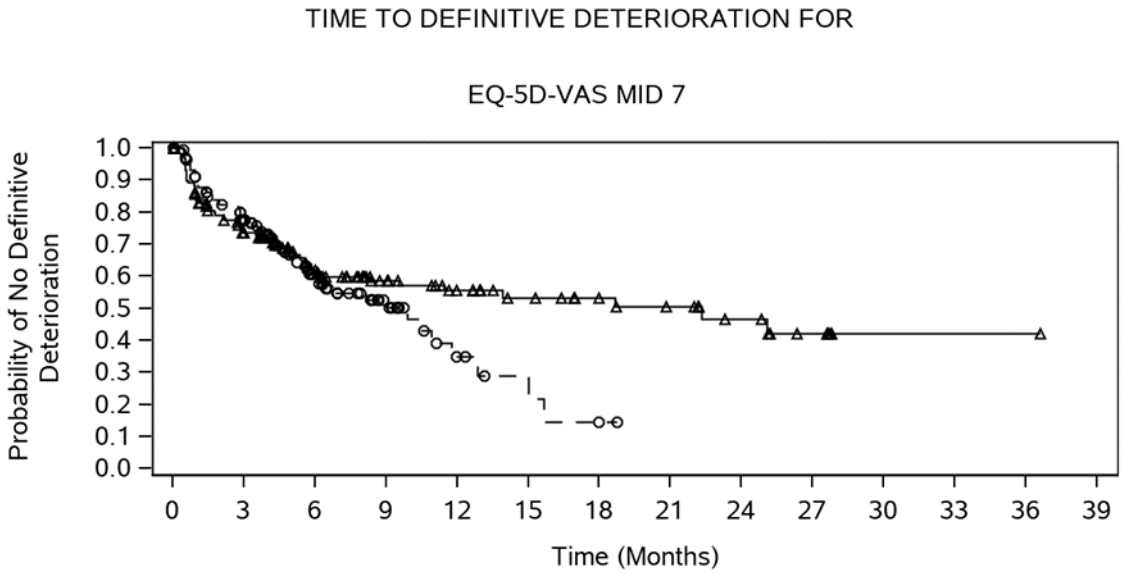
Overall Survival: Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Overall Survival Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95% CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95% CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95% CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.1642
< 10%	55	41 (74.5)	14.62 (10.28, 19.29)	60	55 (91.7)	7.69 (6.51, 9.63)	0.489 (0.323, 0.741) 0.0006	
>= 10%	103	78 (75.7)	13.04 (9.49, 19.78)	97	75 (77.3)	9.63 (8.51, 12.19)	0.747 (0.542, 1.030) 0.0749	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.4957
< 5%	38	29 (76.3)	14.62 (8.71, 25.30)	42	39 (92.9)	7.61 (6.51, 9.63)	0.531 (0.325, 0.869) 0.0105	
>= 5%	120	90 (75.0)	13.04 (11.17, 18.30)	115	91 (79.1)	9.49 (8.11, 11.37)	0.683 (0.508, 0.918) 0.0112	

Oct 2021 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-ossub-503.sas 02MAR2022:12:25:3

2 Gesundheitszustand gemäß EQ-5D VAS (ITT-Population der Patienten mit PD-L1 TC ≥ 1 %)

2.1 KM-Kurven – MID = 7



Number of Subjects at Risk

Nivo + Ipi	154	93	63	42	32	24	19	16	11	6	1	1	1	0
Chemo	143	90	43	21	7	4	1	0	0	0	0	0	0	0

Nivo + Ipi (events: 59/154), median and 95% CI: 22.34 (8.38, N.A.)

Chemo (events: 58/143), median and 95% CI: 9.89 (6.11, 11.76)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.745 (0.510, 1.089), p-value: 0.2705

2.2 Zeit bis zur dauerhaften Verschlechterung (MID = 7, 10, 15)

Protocol: CA209648 Page 1 of 1

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	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)
EQ-5D-VAS (MID=7)	154	59 (38.3)	22.34 (8.38, N.A.)	143	58 (40.6)	9.89 (6.11, 11.76)	0.745 (0.510, 1.089)	0.2705
EQ-5D-VAS (MID=10)	154	56 (36.4)	23.72 (9.53, N.A.)	143	57 (39.9)	9.76 (6.18, 11.76)	0.688 (0.467, 1.013)	0.1497
EQ-5D-VAS (MID=15)	154	39 (25.3)	N.A. (20.76, N.A.)	143	39 (27.3)	10.91 (9.00, N.A.)	0.626 (0.391, 1.001)	0.1489

Oct 2021 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) Stratified Cox proportional hazard model with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank Test
Stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tdd-ebr503.sas 01APR2022:18:55:10

2.3 Zusatzanalyse – Art der Ereignisse und Zensierungen für die Zeit bis zur dauerhaften Verschlechterung (MID = 7, 10, 15)

Protocol: CA209648 Page 1 of 2

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
EQ-5D-VAS (MID=7)		
EVENT:	59/154 (38.3%)	58/143 (40.6%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	2/ 59 (3.4%)	3/ 58 (5.2%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	21/ 59 (35.6%)	30/ 58 (51.7%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	36/ 59 (61.0%)	25/ 58 (43.1%)
CENSORED:	95/154 (61.7%)	85/143 (59.4%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	39/ 95 (41.1%)	26/ 85 (30.6%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	56/ 95 (58.9%)	59/ 85 (69.4%)
EQ-5D-VAS (MID=10)		
EVENT:	56/154 (36.4%)	57/143 (39.9%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	1/ 56 (1.8%)	3/ 57 (5.3%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	19/ 56 (33.9%)	30/ 57 (52.6%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	36/ 56 (64.3%)	24/ 57 (42.1%)
CENSORED:	98/154 (63.6%)	86/143 (60.1%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	38/ 98 (38.8%)	26/ 86 (30.2%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	60/ 98 (61.2%)	60/ 86 (69.8%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:28:51

Protocol: CA209648 Page 2 of 2

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
EQ-5D-VAS (MID=15)		
EVENT:	39/154 (25.3%)	39/143 (27.3%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	2/ 39 (5.1%)	5/ 39 (12.8%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	20/ 39 (51.3%)	20/ 39 (51.3%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	17/ 39 (43.6%)	14/ 39 (35.9%)
CENSORED:	115/154 (74.7%)	104/143 (72.7%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	31/115 (27.0%)	20/104 (19.2%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	84/115 (73.0%)	84/104 (80.8%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:28:51

2.4 Subgruppenanalysen – MID = 7, 10, 15

Protocol: CA209648 Page 1 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	154	59 (38.3)	22.34 (8.38, N.A.)	143	58 (40.6)	9.89 (6.11, 11.76)	0.720 (0.494, 1.050) 0.1973	
AGE								0.7545
< 65	91	35 (38.5)	25.07 (5.55, N.A.)	75	30 (40.0)	9.89 (4.93, 15.67)	0.832 (0.506, 1.370) 0.6235	
>= 65 AND < 75	55	22 (40.0)	18.66 (5.68, N.A.)	56	26 (46.4)	8.15 (5.03, 10.91)	0.587 (0.318, 1.083) 0.1367	
>= 75	8	2 (25.0)	N.A. (0.66, N.A.)	12	2 (16.7)	N.A. (4.70, N.A.)	0.606 (0.067, 5.487) 0.9602	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 2 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4372
MALE	127	46 (36.2)	22.34 (9.53, N.A.)	122	46 (37.7)	9.89 (6.11, 15.67)	0.758 (0.496, 1.158) 0.3890	
FEMALE	27	13 (48.1)	6.11 (4.96, N.A.)	21	12 (57.1)	9.00 (1.45, 12.88)	0.586 (0.256, 1.338) 0.2071	
RACE								0.1891
ASIAN	117	49 (41.9)	13.93 (5.68, N.A.)	105	43 (41.0)	10.51 (5.68, 12.88)	0.803 (0.524, 1.228) 0.5230	
NON-ASIAN	37	10 (27.0)	N.A. (5.36, N.A.)	38	15 (39.5)	6.57 (4.53, 15.01)	0.492 (0.215, 1.127) 0.1206	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 3 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.3628
J/K/T	91	38 (41.8)	18.66 (5.68, N.A.)	86	34 (39.5)	10.91 (5.78, 15.67)	0.818 (0.503, 1.329) 0.6742	
REST OF ASIA	25	11 (44.0)	6.24 (2.73, N.A.)	19	9 (47.4)	5.03 (1.51, N.A.)	0.785 (0.316, 1.951) 0.5092	
REST OF WORLD	38	10 (26.3)	N.A. (8.38, N.A.)	38	15 (39.5)	6.57 (4.53, 15.01)	0.472 (0.206, 1.081) 0.0978	
REGION								0.1526
ASIA	116	49 (42.2)	13.93 (5.68, N.A.)	105	43 (41.0)	10.51 (5.68, 12.88)	0.815 (0.532, 1.247) 0.5709	
NON-ASIA	38	10 (26.3)	N.A. (8.38, N.A.)	38	15 (39.5)	6.57 (4.53, 15.01)	0.472 (0.206, 1.081) 0.0978	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 4 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.5297
0	71	31 (43.7)	13.93 (5.65, N.A.)	69	28 (40.6)	10.91 (5.78, 15.67)	0.758 (0.445, 1.290) 0.6112	
1	83	28 (33.7)	25.07 (5.68, N.A.)	72	29 (40.3)	6.57 (4.96, N.A.)	0.716 (0.417, 1.231) 0.2727	
WEIGHT								0.3552
< 60 KG	94	29 (30.9)	N.A. (13.93, N.A.)	76	30 (39.5)	10.51 (5.68, 15.01)	0.594 (0.348, 1.014) 0.1157	
>= 60 KG	60	30 (50.0)	9.53 (4.30, N.A.)	67	28 (41.8)	8.15 (4.30, N.A.)	0.867 (0.507, 1.481) 0.7750	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 5 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8859
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	3 (60.0)	4.73 (0.62, N.A.)	0.387 (0.058, 2.587) 0.3238	
STAGE II	5	3 (60.0)	5.65 (0.99, N.A.)	5	0	N.E.	N.E. 0.2370	
STAGE III	30	11 (36.7)	N.A. (5.55, N.A.)	45	18 (40.0)	10.51 (6.11, 15.67)	0.758 (0.353, 1.627) 0.5925	
STAGE IV	113	42 (37.2)	22.34 (6.24, N.A.)	88	37 (42.0)	9.00 (4.93, 15.01)	0.672 (0.422, 1.069) 0.2005	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8506
GX	11	5 (45.5)	N.A. (0.53, N.A.)	14	7 (50.0)	5.68 (1.94, N.A.)	0.968 (0.294, 3.185) 0.8447	
G1	8	2 (25.0)	N.A. (0.49, N.A.)	8	5 (62.5)	5.42 (2.76, N.A.)	0.445 (0.084, 2.358) 0.3367	
G2	56	23 (41.1)	25.07 (5.36, N.A.)	49	19 (38.8)	12.88 (3.58, N.A.)	0.707 (0.378, 1.323) 0.4299	
G3	27	10 (37.0)	N.A. (4.30, N.A.)	36	13 (36.1)	10.51 (6.57, N.A.)	0.773 (0.324, 1.845) 0.5780	
NOT OTHERWISE SPECIFIED	50	19 (38.0)	18.66 (5.68, N.A.)	36	14 (38.9)	9.00 (4.96, N.A.)	0.733 (0.358, 1.497) 0.6254	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 7 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.3517
UPPER THORACIC	35	9 (25.7)	N.A. (11.43, N.A.)	26	13 (50.0)	6.47 (4.96, 9.89)	0.419 (0.176, 0.999) 0.0513	
MIDDLE THORACIC	49	23 (46.9)	6.24 (4.63, N.A.)	51	22 (43.1)	11.76 (4.53, 15.01)	0.704 (0.372, 1.334) 0.6671	
LOWER THORACIC	59	26 (44.1)	13.93 (5.13, N.A.)	58	19 (32.8)	10.51 (5.78, N.A.)	1.084 (0.589, 1.993) 0.6657	
GASTROESOPHAGEAL JUNCTION	10	0	N.E.	8	4 (50.0)	6.18 (0.53, N.A.)	N.E. 0.0219	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 8 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.2277
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (0.53, N.A.)	12	6 (50.0)	8.15 (1.45, N.A.)	0.300 (0.036, 2.514) 0.2210	
RECURRENT - DISTANT	23	13 (56.5)	5.65 (1.48, N.A.)	27	9 (33.3)	10.51 (4.96, N.A.)	1.576 (0.670, 3.703) 0.2681	
DE NOVO METASTATIC	106	38 (35.8)	22.34 (11.43, N.A.)	80	35 (43.8)	9.00 (4.53, 12.88)	0.625 (0.386, 1.012) 0.1264	
UNRESECTABLE ADVANCED	18	7 (38.9)	25.07 (4.30, N.A.)	24	8 (33.3)	11.76 (3.84, N.A.)	0.650 (0.219, 1.934) 0.4973	
SMOKING STATUS								0.5090
CURRENT/FORMER	132	52 (39.4)	18.66 (8.38, N.A.)	111	44 (39.6)	9.89 (5.68, 15.67)	0.748 (0.492, 1.136) 0.3688	
NEVER/UNKNOWN	22	7 (31.8)	N.A. (5.13, N.A.)	32	14 (43.8)	10.91 (3.58, 15.01)	0.606 (0.236, 1.555) 0.3365	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 9 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.9765
CURRENT/FORMER	122	46 (37.7)	22.34 (8.38, N.A.)	117	48 (41.0)	9.89 (5.78, 12.88)	0.697 (0.458, 1.061) 0.1714	
NEVER/UNKNOWN	32	13 (40.6)	N.A. (2.76, N.A.)	26	10 (38.5)	6.57 (4.53, N.A.)	1.015 (0.412, 2.501) 0.8790	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.3128
<= 1	78	24 (30.8)	22.34 (18.66, N.A.)	68	27 (39.7)	10.91 (4.70, N.A.)	0.574 (0.324, 1.016) 0.0757	
>= 2	76	35 (46.1)	9.53 (3.55, N.A.)	75	31 (41.3)	9.00 (5.68, 10.51)	0.860 (0.516, 1.431) 0.9155	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 10 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2517
< 1 YEAR	127	47 (37.0)	22.34 (9.53, N.A.)	114	46 (40.4)	9.00 (5.68, 12.88)	0.637 (0.415, 0.978) 0.0983	
1 - < 3 YEARS	23	10 (43.5)	2.79 (0.95, N.A.)	20	8 (40.0)	10.51 (1.45, N.A.)	1.228 (0.482, 3.130) 0.6922	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.2964
YES	36	15 (41.7)	9.53 (5.55, N.A.)	36	13 (36.1)	10.51 (5.03, N.A.)	1.040 (0.493, 2.195) 0.9831	
NO	118	44 (37.3)	22.34 (11.43, N.A.)	107	45 (42.1)	9.00 (5.42, 12.88)	0.631 (0.406, 0.980) 0.1371	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 11 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.0680
YES	23	12 (52.2)	2.89 (1.48, N.A.)	25	9 (36.0)	10.91 (5.03, N.A.)	1.693 (0.709, 4.046) 0.2393	
NO	131	47 (35.9)	22.34 (11.43, N.A.)	118	49 (41.5)	9.89 (5.68, 12.88)	0.608 (0.399, 0.927) 0.0581	
PD-L1 CPS I								0.3190
< 10	50	19 (38.0)	25.07 (3.55, N.A.)	52	17 (32.7)	N.A. (4.70, N.A.)	0.941 (0.478, 1.850) 0.9106	
>= 10	91	34 (37.4)	22.34 (5.68, N.A.)	89	41 (46.1)	9.00 (5.68, 11.76)	0.597 (0.371, 0.963) 0.0664	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 12 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.8552
< 5	28	10 (35.7)	25.07 (3.48, N.A.)	22	9 (40.9)	6.11 (3.84, N.A.)	0.780 (0.307, 1.981) 0.8298	
>= 5	113	43 (38.1)	22.34 (8.38, N.A.)	119	49 (41.2)	9.89 (6.18, 11.76)	0.690 (0.451, 1.054) 0.1494	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.6099
< 10%	53	23 (43.4)	9.53 (4.96, N.A.)	56	22 (39.3)	9.00 (4.70, N.A.)	0.757 (0.411, 1.396) 0.7229	
>= 10%	101	36 (35.6)	22.34 (6.24, N.A.)	87	36 (41.4)	9.89 (5.78, 12.88)	0.676 (0.417, 1.098) 0.1622	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 13 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.4785
< 5%	37	16 (43.2)	9.53 (4.01, N.A.)	40	16 (40.0)	9.00 (4.53, N.A.)	0.830 (0.406, 1.697) 0.7735	
>= 5%	117	43 (36.8)	22.34 (6.24, N.A.)	103	42 (40.8)	9.89 (6.18, 12.88)	0.677 (0.433, 1.058) 0.1621	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 14 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	154	56 (36.4)	23.72 (9.53, N.A.)	143	57 (39.9)	9.76 (6.18, 11.76)	0.679 (0.463, 0.997) 0.1235	
AGE								0.9133
< 65	91	32 (35.2)	25.07 (6.24, N.A.)	75	30 (40.0)	9.89 (5.42, 15.67)	0.741 (0.446, 1.233) 0.3541	
>= 65 AND < 75	55	22 (40.0)	18.66 (5.68, N.A.)	56	25 (44.6)	8.15 (5.03, 10.91)	0.600 (0.323, 1.114) 0.1759	
>= 75	8	2 (25.0)	N.A. (0.66, N.A.)	12	2 (16.7)	N.A. (4.70, N.A.)	0.606 (0.067, 5.487) 0.9602	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 15 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5040
MALE	127	43 (33.9)	25.07 (11.43, N.A.)	122	45 (36.9)	9.76 (6.18, 15.67)	0.701 (0.454, 1.082) 0.2440	
FEMALE	27	13 (48.1)	6.11 (4.96, N.A.)	21	12 (57.1)	9.00 (1.45, 12.88)	0.586 (0.256, 1.338) 0.2071	
RACE								0.2052
ASIAN	117	47 (40.2)	18.66 (6.24, N.A.)	105	43 (41.0)	9.76 (5.78, 11.76)	0.755 (0.491, 1.160) 0.3622	
NON-ASIAN	37	9 (24.3)	N.A. (5.36, N.A.)	38	14 (36.8)	9.89 (4.70, N.A.)	0.472 (0.198, 1.123) 0.1298	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 16 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.3865
J/K/T	91	37 (40.7)	18.66 (6.11, N.A.)	86	34 (39.5)	10.91 (5.78, 15.67)	0.769 (0.471, 1.257) 0.5406	
REST OF ASIA	25	10 (40.0)	11.43 (3.55, N.A.)	19	9 (47.4)	9.00 (1.51, N.A.)	0.738 (0.286, 1.903) 0.3931	
REST OF WORLD	38	9 (23.7)	N.A.	38	14 (36.8)	9.89 (4.70, N.A.)	0.453 (0.190, 1.078) 0.1068	
REGION								0.1678
ASIA	116	47 (40.5)	13.93 (6.24, N.A.)	105	43 (41.0)	9.76 (5.78, 11.76)	0.766 (0.499, 1.178) 0.4019	
NON-ASIA	38	9 (23.7)	N.A.	38	14 (36.8)	9.89 (4.70, N.A.)	0.453 (0.190, 1.078) 0.1068	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 17 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7106
0	71	29 (40.8)	18.66 (8.34, N.A.)	69	28 (40.6)	10.91 (5.78, 15.67)	0.676 (0.392, 1.163) 0.4101	
1	83	27 (32.5)	25.07 (6.24, N.A.)	72	28 (38.9)	9.76 (5.03, 10.51)	0.700 (0.402, 1.216) 0.2433	
WEIGHT								0.3621
< 60 KG	94	28 (29.8)	N.A. (13.93, N.A.)	76	30 (39.5)	10.51 (5.68, 15.01)	0.563 (0.328, 0.967) 0.0876	
>= 60 KG	60	28 (46.7)	11.43 (4.96, N.A.)	67	27 (40.3)	8.15 (4.70, 11.76)	0.805 (0.465, 1.394) 0.5868	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 18 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9049
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	3 (60.0)	4.73 (0.62, N.A.)	0.387 (0.058, 2.587) 0.3238	
STAGE II	5	2 (40.0)	N.A. (0.99, N.A.)	5	0	N.E.	N.E. 0.3431	
STAGE III	30	10 (33.3)	N.A. (5.55, N.A.)	45	17 (37.8)	10.91 (6.11, 15.67)	0.708 (0.319, 1.571) 0.5213	
STAGE IV	113	41 (36.3)	23.72 (8.34, N.A.)	88	37 (42.0)	9.00 (5.42, 12.88)	0.640 (0.401, 1.020) 0.1291	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 19 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8577
GX	11	5 (45.5)	N.A. (0.53, N.A.)	14	7 (50.0)	5.68 (1.94, N.A.)	0.968 (0.294, 3.185) 0.8447	
G1	8	2 (25.0)	N.A. (0.49, N.A.)	8	5 (62.5)	5.42 (2.76, N.A.)	0.445 (0.084, 2.358) 0.3367	
G2	56	21 (37.5)	25.07 (5.36, N.A.)	49	18 (36.7)	12.88 (3.58, N.A.)	0.655 (0.341, 1.256) 0.3791	
G3	27	10 (37.0)	N.A. (4.30, N.A.)	36	13 (36.1)	9.89 (9.76, N.A.)	0.756 (0.317, 1.805) 0.5365	
NOT OTHERWISE SPECIFIED	50	18 (36.0)	18.66 (6.11, N.A.)	36	14 (38.9)	9.00 (4.96, N.A.)	0.660 (0.320, 1.362) 0.4354	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 20 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.2514
UPPER THORACIC	35	8 (22.9)	N.A. (8.34, N.A.)	26	13 (50.0)	6.47 (4.96, 9.89)	0.344 (0.140, 0.846) 0.0170	
MIDDLE THORACIC	49	22 (44.9)	23.72 (4.63, N.A.)	51	22 (43.1)	11.76 (4.53, 15.01)	0.651 (0.339, 1.248) 0.5647	
LOWER THORACIC	59	25 (42.4)	13.93 (5.13, N.A.)	58	19 (32.8)	10.51 (6.57, N.A.)	1.045 (0.565, 1.932) 0.7690	
GASTROESOPHAGEAL JUNCTION	10	0	N.E.	8	3 (37.5)	6.18 (0.53, N.A.)	N.E. 0.0503	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 21 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3515
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (0.53, N.A.)	12	6 (50.0)	8.15 (1.45, N.A.)	0.300 (0.036, 2.514) 0.2210	
RECURRENT - DISTANT	23	11 (47.8)	5.68 (1.48, N.A.)	27	9 (33.3)	10.51 (4.96, N.A.)	1.351 (0.557, 3.278) 0.4833	
DE NOVO METASTATIC	106	37 (34.9)	23.72 (11.43, N.A.)	80	35 (43.8)	9.00 (4.70, 12.88)	0.591 (0.364, 0.960) 0.0737	
UNRESECTABLE ADVANCED	18	7 (38.9)	25.07 (4.30, N.A.)	24	7 (29.2)	11.76 (5.42, N.A.)	0.708 (0.230, 2.181) 0.6605	
SMOKING STATUS								0.7084
CURRENT/FORMER	132	49 (37.1)	23.72 (9.53, N.A.)	111	44 (39.6)	9.76 (5.78, 11.76)	0.689 (0.451, 1.054) 0.2064	
NEVER/UNKNOWN	22	7 (31.8)	N.A. (5.13, N.A.)	32	13 (40.6)	10.91 (4.14, 15.01)	0.616 (0.237, 1.603) 0.4236	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 22 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.8657
CURRENT/FORMER	122	44 (36.1)	23.72 (9.53, N.A.)	117	47 (40.2)	9.89 (6.11, 11.76)	0.664 (0.433, 1.018) 0.1228	
NEVER/UNKNOWN	32	12 (37.5)	N.A. (4.17, N.A.)	26	10 (38.5)	6.57 (4.53, N.A.)	0.933 (0.372, 2.341) 0.7114	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.3753
<= 1	78	22 (28.2)	23.72 (18.66, N.A.)	68	26 (38.2)	10.91 (5.78, N.A.)	0.538 (0.298, 0.972) 0.0565	
>= 2	76	34 (44.7)	9.53 (4.63, N.A.)	75	31 (41.3)	9.00 (5.68, 10.51)	0.801 (0.479, 1.341) 0.7148	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 23 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2284
< 1 YEAR	127	45 (35.4)	23.72 (9.53, N.A.)	114	45 (39.5)	9.76 (5.78, 12.88)	0.608 (0.394, 0.940) 0.0667	
1 - < 3 YEARS	23	10 (43.5)	2.79 (0.95, N.A.)	20	8 (40.0)	10.51 (1.45, N.A.)	1.228 (0.482, 3.130) 0.6922	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.3437
YES	36	13 (36.1)	N.A. (5.55, N.A.)	36	12 (33.3)	10.51 (5.03, N.A.)	0.992 (0.451, 2.180) 0.8954	
NO	118	43 (36.4)	23.72 (8.34, N.A.)	107	45 (42.1)	9.76 (5.68, 12.88)	0.605 (0.389, 0.942) 0.0898	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 24 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.0908
YES	23	11 (47.8)	2.89 (1.48, N.A.)	25	9 (36.0)	10.91 (5.03, N.A.)	1.536 (0.632, 3.734) 0.3548	
NO	131	45 (34.4)	23.72 (11.43, N.A.)	118	48 (40.7)	9.76 (6.11, 11.76)	0.580 (0.378, 0.891) 0.0378	
PD-L1 CPS I								0.1985
< 10	50	19 (38.0)	25.07 (3.55, N.A.)	52	17 (32.7)	9.76 (4.93, N.A.)	0.959 (0.490, 1.877) 0.9428	
>= 10	91	31 (34.1)	23.72 (8.34, N.A.)	89	40 (44.9)	9.00 (5.78, 11.76)	0.529 (0.323, 0.867) 0.0282	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 25 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.6414
< 5	28	10 (35.7)	25.07 (3.48, N.A.)	22	9 (40.9)	6.11 (3.84, N.A.)	0.835 (0.331, 2.109) 0.7555	
>= 5	113	40 (35.4)	23.72 (9.53, N.A.)	119	48 (40.3)	9.89 (6.18, 12.88)	0.631 (0.408, 0.976) 0.0803	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5688
< 10%	53	22 (41.5)	25.07 (4.96, N.A.)	56	22 (39.3)	9.00 (4.93, N.A.)	0.751 (0.407, 1.386) 0.6358	
>= 10%	101	34 (33.7)	23.72 (11.43, N.A.)	87	35 (40.2)	9.89 (6.18, 12.88)	0.628 (0.382, 1.032) 0.1072	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 26 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=10)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.4634
< 5%	37	15 (40.5)	25.07 (4.01, N.A.)	40	16 (40.0)	9.00 (4.70, N.A.)	0.828 (0.403, 1.702) 0.6711	
>= 5%	117	41 (35.0)	23.72 (11.43, N.A.)	103	41 (39.8)	9.89 (6.18, 12.88)	0.634 (0.402, 1.001) 0.1114	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 27 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	154	39 (25.3)	N.A. (20.76, N.A.)	143	39 (27.3)	10.91 (9.00, N.A.)	0.616 (0.386, 0.983) 0.1386	
AGE								0.9889
< 65	91	21 (23.1)	N.A. (12.48, N.A.)	75	20 (26.7)	12.88 (8.54, N.A.)	0.621 (0.329, 1.169) 0.2638	
>= 65 AND < 75	55	16 (29.1)	21.22 (19.02, N.A.)	56	17 (30.4)	10.51 (7.62, N.A.)	0.636 (0.307, 1.319) 0.3798	
>= 75	8	2 (25.0)	N.A. (1.61, N.A.)	12	2 (16.7)	N.A. (4.14, N.A.)	0.597 (0.068, 5.237) 0.8783	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 28 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1007
MALE	127	31 (24.4)	N.A. (19.02, N.A.)	122	28 (23.0)	N.A. (8.54, N.A.)	0.734 (0.431, 1.251) 0.5844	
FEMALE	27	8 (29.6)	21.22 (5.36, N.A.)	21	11 (52.4)	9.00 (1.45, 12.88)	0.362 (0.134, 0.976) 0.0373	
RACE								0.1064
ASIAN	117	34 (29.1)	21.22 (12.48, N.A.)	105	29 (27.6)	10.91 (8.54, N.A.)	0.730 (0.434, 1.228) 0.4909	
NON-ASIAN	37	5 (13.5)	N.A.	38	10 (26.3)	15.01 (5.55, N.A.)	0.331 (0.109, 1.003) 0.0746	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 29 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.1801
J/K/T	91	28 (30.8)	21.22 (12.48, N.A.)	86	22 (25.6)	12.88 (8.54, N.A.)	0.850 (0.470, 1.539) 0.9924	
REST OF ASIA	25	6 (24.0)	N.A. (5.52, N.A.)	19	7 (36.8)	9.76 (3.38, N.A.)	0.433 (0.134, 1.397) 0.0986	
REST OF WORLD	38	5 (13.2)	N.A.	38	10 (26.3)	15.01 (5.55, N.A.)	0.319 (0.105, 0.965) 0.0626	
REGION								0.0892
ASIA	116	34 (29.3)	21.22 (12.48, N.A.)	105	29 (27.6)	10.91 (8.54, N.A.)	0.741 (0.440, 1.247) 0.5320	
NON-ASIA	38	5 (13.2)	N.A.	38	10 (26.3)	15.01 (5.55, N.A.)	0.319 (0.105, 0.965) 0.0626	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 30 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.1215
0	71	24 (33.8)	20.76 (12.48, N.A.)	69	17 (24.6)	12.88 (8.54, N.A.)	0.766 (0.394, 1.491) 0.9577	
1	83	15 (18.1)	N.A.	72	21 (29.2)	9.76 (6.14, N.A.)	0.485 (0.243, 0.969) 0.0484	
WEIGHT								0.5800
< 60 KG	94	22 (23.4)	21.22 (19.02, N.A.)	76	22 (28.9)	10.91 (8.25, 15.01)	0.517 (0.273, 0.978) 0.0905	
>= 60 KG	60	17 (28.3)	N.A. (12.48, N.A.)	67	17 (25.4)	N.A. (7.62, N.A.)	0.761 (0.383, 1.512) 0.6983	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 31 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9187
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	2 (40.0)	8.54 (6.14, N.A.)	0.841 (0.115, 6.180) 0.9873	
STAGE II	5	1 (20.0)	N.A. (3.84, N.A.)	5	0	N.E.	N.E. 0.5637	
STAGE III	30	8 (26.7)	N.A. (9.53, N.A.)	45	11 (24.4)	10.91 (6.18, N.A.)	0.760 (0.292, 1.974) 0.7171	
STAGE IV	113	27 (23.9)	N.A. (19.02, N.A.)	88	26 (29.5)	9.76 (8.25, 15.01)	0.519 (0.292, 0.922) 0.0771	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 32 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.6939
GX	11	4 (36.4)	N.A. (1.45, N.A.)	14	6 (42.9)	8.54 (2.83, N.A.)	0.855 (0.222, 3.291) 0.8346	
G1	8	1 (12.5)	N.A. (3.84, N.A.)	8	4 (50.0)	8.25 (4.14, N.A.)	0.182 (0.016, 2.111) 0.1549	
G2	56	13 (23.2)	N.A. (20.76, N.A.)	49	11 (22.4)	15.01 (6.18, N.A.)	0.601 (0.260, 1.386) 0.3663	
G3	27	6 (22.2)	N.A. (5.52, N.A.)	36	9 (25.0)	N.A. (9.76, N.A.)	0.613 (0.203, 1.854) 0.4371	
NOT OTHERWISE SPECIFIED	50	15 (30.0)	12.48 (9.53, N.A.)	36	9 (25.0)	9.00 (7.62, N.A.)	0.715 (0.299, 1.713) 0.7487	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 33 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.4375
UPPER THORACIC	35	6 (17.1)	N.A. (12.48, N.A.)	26	9 (34.6)	8.25 (4.96, N.A.)	0.398 (0.137, 1.159) 0.0866	
MIDDLE THORACIC	49	15 (30.6)	N.A. (6.11, N.A.)	51	16 (31.4)	12.88 (5.68, N.A.)	0.641 (0.297, 1.383) 0.6672	
LOWER THORACIC	59	17 (28.8)	21.22 (19.02, N.A.)	58	12 (20.7)	10.51 (9.76, N.A.)	0.876 (0.401, 1.915) 0.8194	
GASTROESOPHAGEAL JUNCTION	10	0	N.E.	8	2 (25.0)	N.A. (0.53, N.A.)	N.E. 0.1343	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 34 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3953
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (0.53, N.A.)	12	4 (33.3)	10.91 (5.03, N.A.)	0.452 (0.050, 4.083) 0.4443	
RECURRENT - DISTANT	23	8 (34.8)	20.76 (3.71, N.A.)	27	7 (25.9)	10.51 (6.11, N.A.)	1.009 (0.350, 2.910) 0.9636	
DE NOVO METASTATIC	106	25 (23.6)	N.A. (19.02, N.A.)	80	25 (31.3)	9.76 (7.62, 15.01)	0.468 (0.258, 0.849) 0.0430	
UNRESECTABLE ADVANCED	18	5 (27.8)	N.A. (4.30, N.A.)	24	3 (12.5)	N.A. (8.25, N.A.)	1.535 (0.356, 6.627) 0.4664	
SMOKING STATUS								0.2035
CURRENT/FORMER	132	36 (27.3)	N.A. (19.02, N.A.)	111	29 (26.1)	10.51 (8.25, N.A.)	0.700 (0.419, 1.167) 0.4365	
NEVER/UNKNOWN	22	3 (13.6)	N.A. (5.55, N.A.)	32	10 (31.3)	12.88 (9.00, N.A.)	0.340 (0.088, 1.309) 0.1180	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 35 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.1184
CURRENT/FORMER	122	34 (27.9)	N.A. (19.02, N.A.)	117	31 (26.5)	10.91 (8.54, N.A.)	0.707 (0.425, 1.175) 0.3953	
NEVER/UNKNOWN	32	5 (15.6)	N.A.	26	8 (30.8)	9.00 (4.70, N.A.)	0.489 (0.140, 1.703) 0.0858	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9958
<= 1	78	19 (24.4)	N.A. (20.76, N.A.)	68	19 (27.9)	10.91 (8.25, N.A.)	0.634 (0.328, 1.223) 0.2291	
>= 2	76	20 (26.3)	N.A. (11.47, N.A.)	75	20 (26.7)	12.88 (9.00, 15.01)	0.609 (0.311, 1.190) 0.3842	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 36 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.5436
< 1 YEAR	127	31 (24.4)	N.A. (19.02, N.A.)	114	29 (25.4)	12.88 (9.00, N.A.)	0.606 (0.355, 1.033) 0.1768	
1 - < 3 YEARS	23	7 (30.4)	20.76 (2.89, N.A.)	20	7 (35.0)	10.51 (5.03, N.A.)	0.870 (0.288, 2.628) 0.6924	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4740
YES	36	9 (25.0)	20.76 (6.08, N.A.)	36	9 (25.0)	10.91 (6.14, N.A.)	0.789 (0.302, 2.057) 0.5610	
NO	118	30 (25.4)	N.A. (19.02, N.A.)	107	30 (28.0)	12.88 (8.25, N.A.)	0.577 (0.337, 0.987) 0.1958	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 37 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.0740
YES	23	9 (39.1)	20.76 (2.89, N.A.)	25	6 (24.0)	10.91 (5.03, N.A.)	1.571 (0.535, 4.609) 0.4634	
NO	131	30 (22.9)	N.A. (21.22, N.A.)	118	33 (28.0)	10.51 (8.54, N.A.)	0.515 (0.305, 0.870) 0.0475	
PD-L1 CPS I								0.5957
< 10	50	12 (24.0)	N.A. (6.11, N.A.)	52	12 (23.1)	9.76 (5.55, N.A.)	0.810 (0.359, 1.827) 0.7530	
>= 10	91	22 (24.2)	N.A. (20.76, N.A.)	89	27 (30.3)	10.91 (8.54, N.A.)	0.518 (0.285, 0.941) 0.0862	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 38 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.6167
< 5	28	5 (17.9)	N.A. (3.71, N.A.)	22	7 (31.8)	9.76 (5.03, N.A.)	0.562 (0.177, 1.782) 0.3592	
>= 5	113	29 (25.7)	N.A. (20.76, N.A.)	119	32 (26.9)	12.88 (9.00, N.A.)	0.619 (0.366, 1.049) 0.1914	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5534
< 10%	53	17 (32.1)	N.A. (6.08, N.A.)	56	16 (28.6)	9.76 (5.55, N.A.)	0.777 (0.386, 1.562) 0.7302	
>= 10%	101	22 (21.8)	N.A. (19.02, N.A.)	87	23 (26.4)	12.88 (8.54, N.A.)	0.527 (0.281, 0.989) 0.1041	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

Protocol: CA209648 Page 39 of 39

EQ-5D-3L Visual Analogue Scale: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EQ-5D-VAS (MID=15)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2140
< 5%	37	12 (32.4)	N.A. (6.08, N.A.)	40	11 (27.5)	9.76 (5.55, N.A.)	1.013 (0.446, 2.302) 0.9591	
>= 5%	117	27 (23.1)	N.A. (20.76, N.A.)	103	28 (27.2)	12.88 (8.54, N.A.)	0.509 (0.288, 0.900) 0.0746	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:06:54

2.5 Zusatzanalyse – Mittlere Änderung während der Behandlung (MMRM)

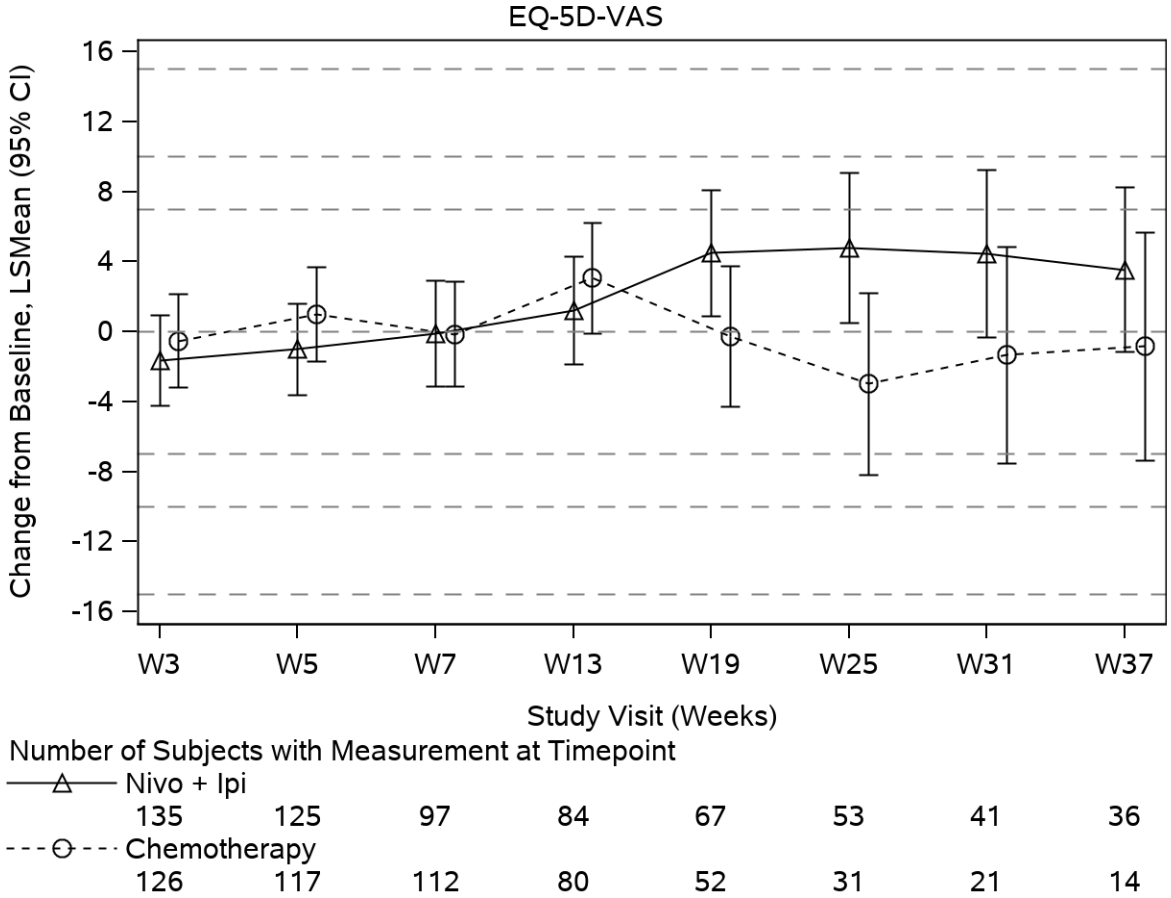
Protocol: CA209648 Page 1 of 1

EQ-5D-3L Visual Analogue Scale: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

EQ-5D-3L Domain	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
EQ-5D-VAS	141	73.3 (19.2)	1.97 (-0.65, 4.58)	133	68.2 (18.4)	-0.25 (-3.21, 2.71)	2.22 (-1.74, 6.18) 0.2697	0.13 (-0.10, 0.37)

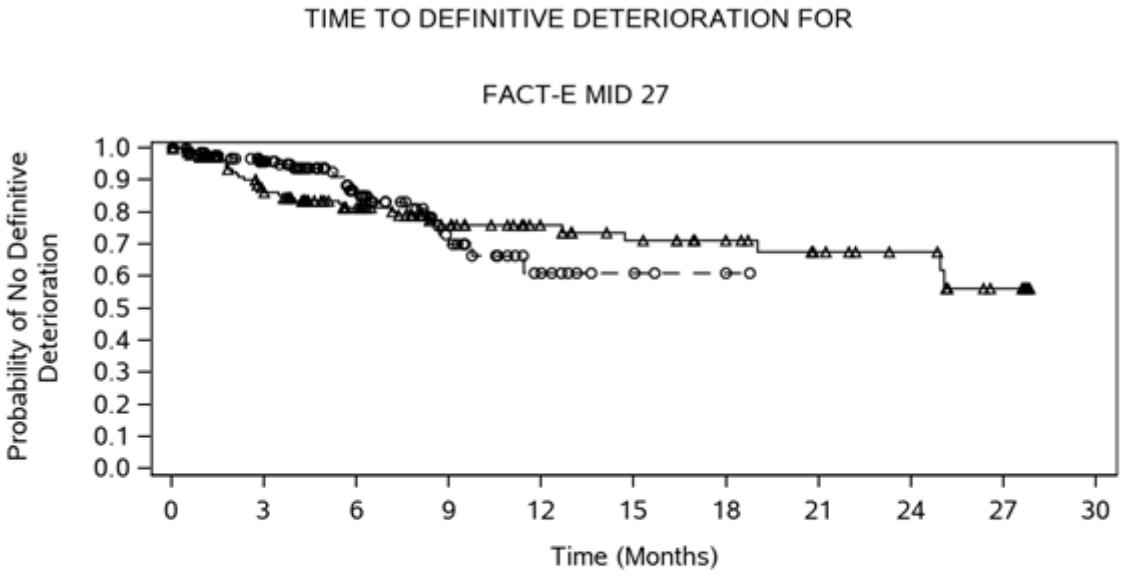
Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:51:24

2.6 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung im Behandlungsverlauf (MMRM)



3 Gesundheitsbezogene Lebensqualität gemäß FACT-E (ITT-Population der Patienten mit PD-L1 TC ≥ 1 %)

3.1 KM-Kurven – FACT-E Gesamtscore (MID = 27)



Number of Subjects at Risk

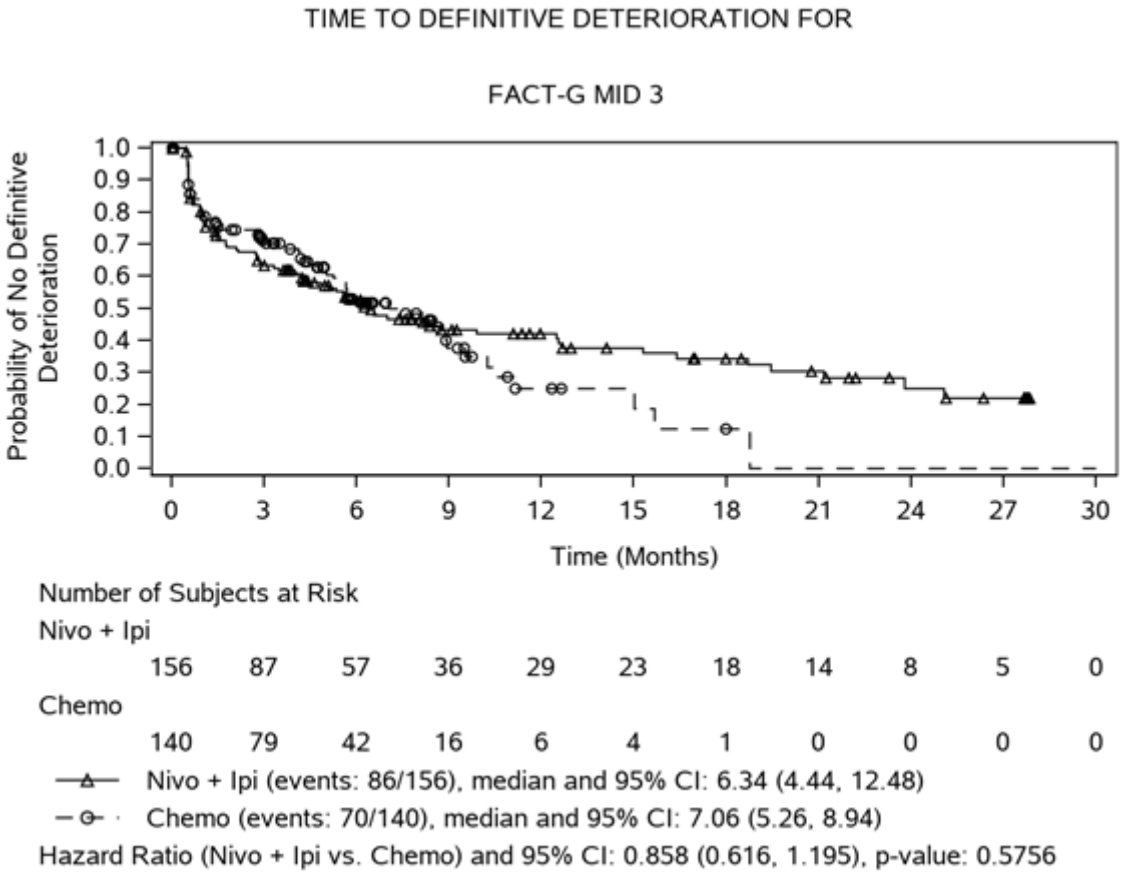
Nivo + Ipi	156	104	73	47	35	28	22	17	13	6	0
Chemo	140	97	53	25	9	4	1	0	0	0	0

Nivo + Ipi (events: 32/156), median and 95% CI: N.A. (24.94, N.A.)

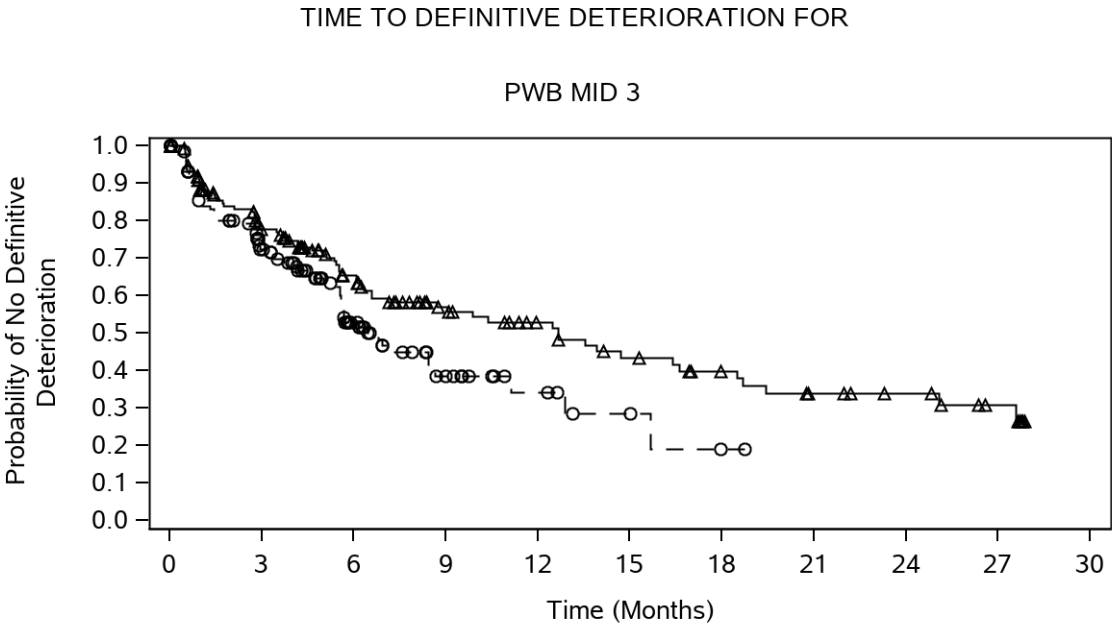
Chemo (events: 21/140), median and 95% CI: N.A. (11.43, N.A.)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 1.053 (0.595, 1.864), p-value: 0.7153

3.2 KM-Kurven – FACT-G Gesamtscore (MID = 3)



3.3 KM-Kurven – FACT-G Subskala PWB (MID = 3)



Number of Subjects at Risk

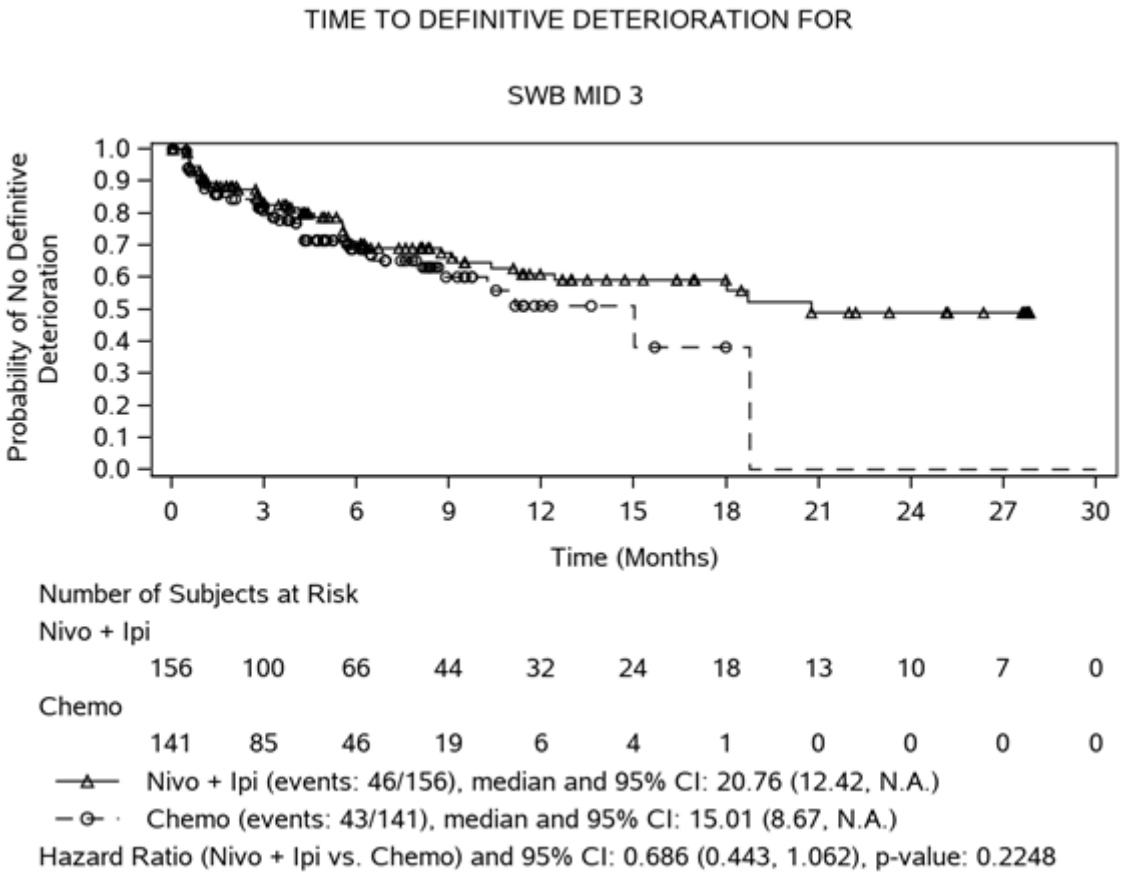
Nivo + Ipi	156	99	66	44	34	26	20	15	12	7	0
Chemo	141	81	39	17	8	4	1	0	0	0	0

Nivo + Ipi (events: 69/156), median and 95% CI: 12.68 (6.57, 18.50)

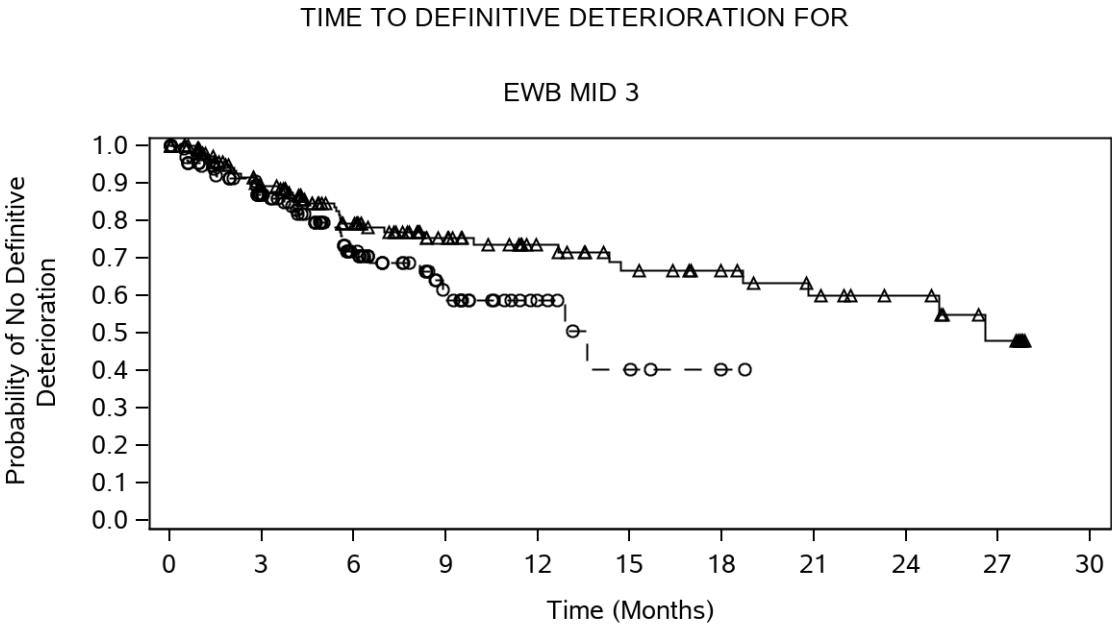
Chemo (events: 64/141), median and 95% CI: 6.47 (5.59, 8.64)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.676 (0.473, 0.968), p-value: 0.0348

3.4 KM-Kurven – FACT-G Subskala SWB (MID = 3)



3.5 KM-Kurven – FACT-G Subskala EWB (MID = 3)



Number of Subjects at Risk

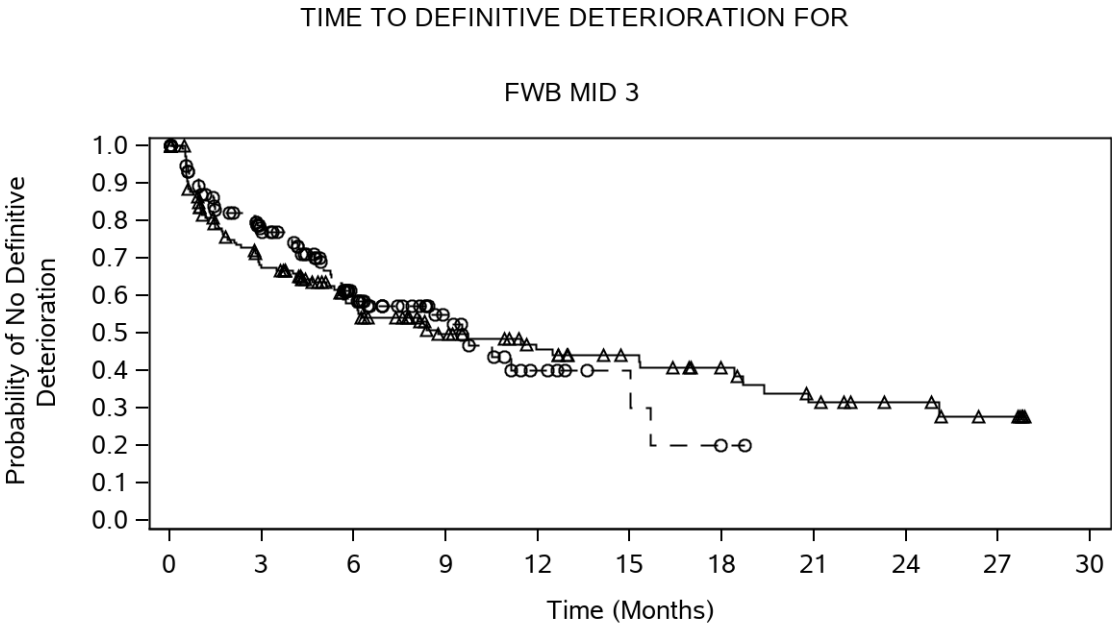
Nivo + Ipi	156	107	72	48	35	27	22	17	13	7	0
Chemo	141	91	49	23	9	4	1	0	0	0	0

Nivo + Ipi (events: 35/156), median and 95% CI: 26.58 (20.83, N.A.)

Chemo (events: 37/141), median and 95% CI: 13.60 (8.90, N.A.)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.598 (0.367, 0.974), p-value: 0.0428

3.6 KM-Kurven – FACT-G Subskala FWB (MID = 3)



Number of Subjects at Risk

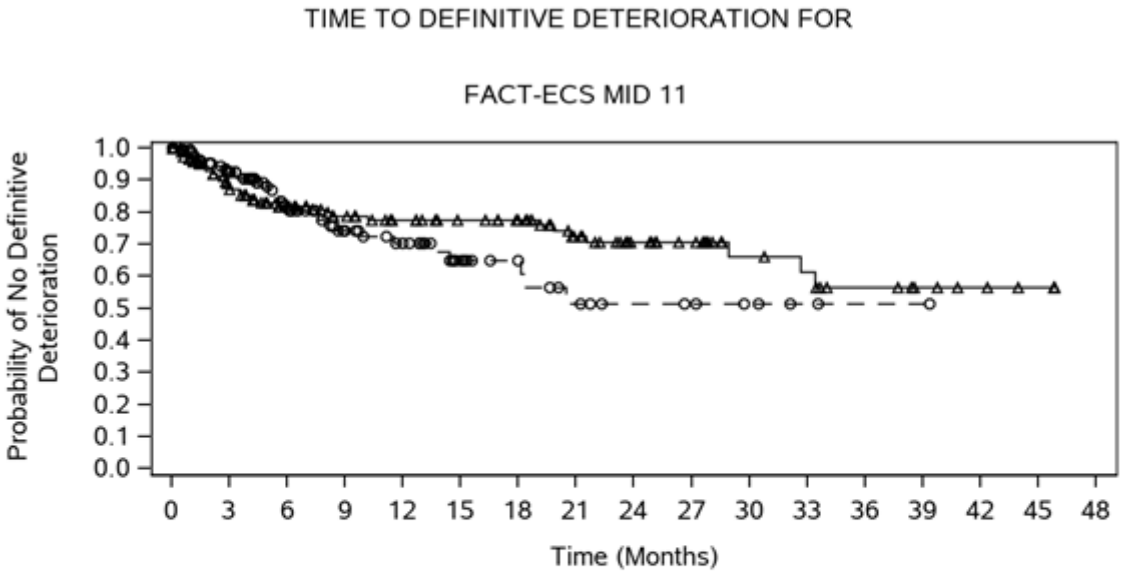
Nivo + Ipi	156	90	62	42	32	25	19	13	9	5	0
Chemo	140	86	46	22	8	4	1	0	0	0	0

Nivo + Ipi (events: 76/156), median and 95% CI: 8.74 (5.65, 18.40)

Chemo (events: 55/140), median and 95% CI: 9.53 (5.91, 15.01)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.988 (0.690, 1.415), p-value: 0.6661

3.7 KM-Kurven – ECS (MID = 11)



Number of Subjects at Risk

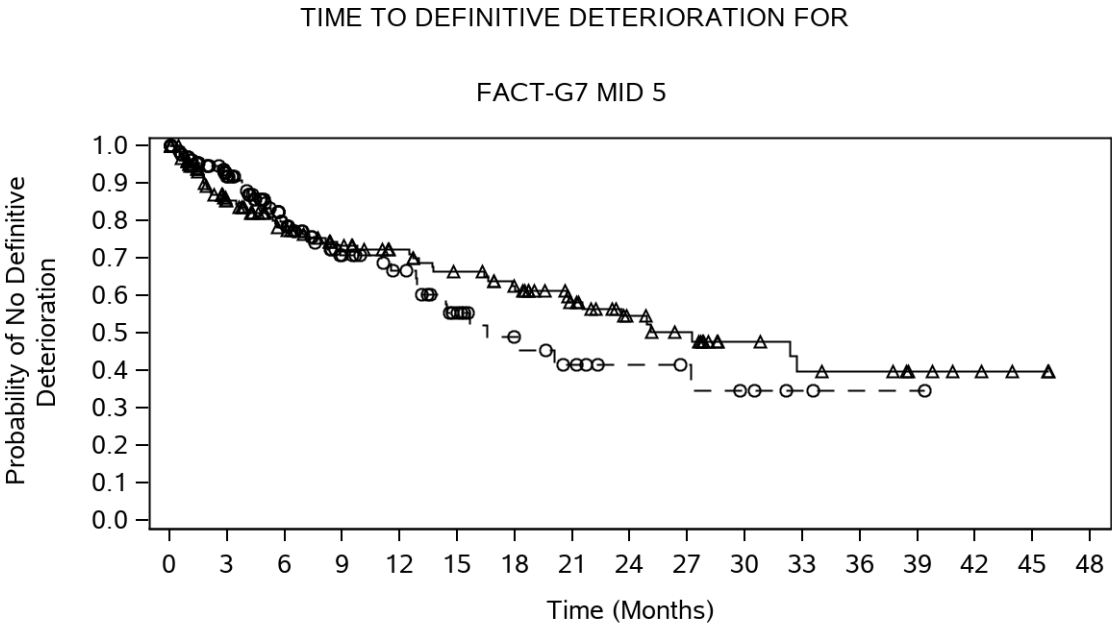
Nivo + Ipi	156	104	85	71	63	57	52	39	29	24	15	13	9	6	4	2	0
Chemo	142	95	61	42	33	21	15	10	7	6	4	2	1	1	0	0	0

—△— Nivo + Ipi (events: 34/156), median and 95% CI: N.A. (32.69, N.A.)

—○— Chemo (events: 30/142), median and 95% CI: N.A. (18.14, N.A.)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.757 (0.455, 1.260), p-value: 0.3043

3.8 KM-Kurven – FACT-G7 Gesamtscore (MID = 5)



Number of Subjects at Risk

Nivo + Ipi	156	103	84	71	63	55	48	36	26	21	13	10	9	6	4	2	0
Chemo	141	97	61	40	32	21	14	10	7	6	4	2	1	1	0	0	0

Nivo + Ipi (events: 52/156), median and 95% CI: 27.24 (20.70, N.A.)

Chemo (events: 39/141), median and 95% CI: 16.56 (12.88, N.A.)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.856 (0.560, 1.310), p-value: 0.5705

3.9 Zeit bis zur dauerhaften Verschlechterung des FACT-G Gesamtscores (MID = 3, 7, 17)

Protocol: CA209648 Page 1 of 1

FACT-G: Time to Definitive Deterioration
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	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)
FACT-G (MID=3)	156	86 (55.1)	6.34 (4.44, 12.48)	140	70 (50.0)	7.06 (5.26, 8.94)	0.858 (0.616, 1.195)	0.5756
FACT-G (MID=7)	156	73 (46.8)	11.86 (6.01, 18.69)	140	57 (40.7)	8.90 (6.47, 11.99)	0.905 (0.628, 1.302)	0.7509
FACT-G (MID=17)	156	34 (21.8)	N.A. (18.69, N.A.)	140	29 (20.7)	15.67 (9.00, N.A.)	0.736 (0.439, 1.236)	0.4002

Oct 2021 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) Stratified Cox proportional hazard model with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank Test
Stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tdd-ebr503.sas 01APR2022:18:55:43

3.10 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala PWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 1

PWB: Time to Definitive Deterioration
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	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)
PWB (MID=2)	156	74 (47.4)	9.95 (6.11, 16.39)	141	78 (55.3)	5.59 (4.21, 6.80)	0.636 (0.457, 0.885)	0.0079
PWB (MID=3)	156	69 (44.2)	12.68 (6.57, 18.50)	141	64 (45.4)	6.47 (5.59, 8.64)	0.676 (0.473, 0.968)	0.0348
PWB (MID=5)	156	47 (30.1)	21.22 (12.48, N.A.)	141	46 (32.6)	8.90 (8.15, N.A.)	0.666 (0.436, 1.016)	0.0607

Oct 2021 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) Stratified Cox proportional hazard model with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank Test
Stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tdd-ebr503.sas 25FEB2022:11:48:3

3.11 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala SWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 1

SWB: Time to Definitive Deterioration
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy		
	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)
SWB (MID=2)	156	63 (40.4)	16.39 (8.74, 21.98)	141	48 (34.0)	11.14 (7.98, N.A.)	0.821 (0.552, 1.219)		0.6849
SWB (MID=3)	156	46 (29.5)	20.76 (12.42, N.A.)	141	43 (30.5)	15.01 (8.67, N.A.)	0.686 (0.443, 1.062)		0.2248
SWB (MID=5)	156	28 (17.9)	N.A. (19.02, N.A.)	141	23 (16.3)	15.01 (11.14, N.A.)	0.736 (0.412, 1.313)		0.5067

Oct 2021 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) Stratified Cox proportional hazard model with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank Test
Stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tdd-ebr503.sas 01APR2022:18:56:00

3.12 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala EWB (MID = 2, 3, 4)

Protocol: CA209648 Page 1 of 1

EWB: Time to Definitive Deterioration
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	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)
EWB (MID=2)	156	48 (30.8)	18.69 (13.60, N.A.)	141	53 (37.6)	9.00 (7.62, 15.67)	0.556 (0.368, 0.841)	0.0069
EWB (MID=3)	156	35 (22.4)	26.58 (20.83, N.A.)	141	37 (26.2)	13.60 (8.90, N.A.)	0.598 (0.367, 0.974)	0.0428
EWB (MID=4)	156	27 (17.3)	27.83 (20.83, N.A.)	141	27 (19.1)	13.60 (12.88, N.A.)	0.586 (0.331, 1.037)	0.0693

Oct 2021 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) Stratified Cox proportional hazard model with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank Test
Stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tdd-ebr503.sas 25FEB2022:11:49:01

3.13 Zeit bis zur dauerhaften Verschlechterung der FACT-G Subskala FWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 1

FWB: Time to Definitive Deterioration
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	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)
FWB (MID=2)	156	84 (53.8)	6.11 (4.63, 11.96)	140	63 (45.0)	8.54 (5.68, 11.14)	0.956 (0.681, 1.340)	0.8570
FWB (MID=3)	156	76 (48.7)	8.74 (5.65, 18.40)	140	55 (39.3)	9.53 (5.91, 15.01)	0.988 (0.690, 1.415)	0.6661
FWB (MID=5)	156	58 (37.2)	18.40 (8.74, 25.07)	140	39 (27.9)	15.01 (8.67, N.A.)	1.055 (0.694, 1.604)	0.4658

Oct 2021 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) Stratified Cox proportional hazard model with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank Test
Stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tdd-ebr503.sas 25FEB2022:11:49:11

3.14 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-E Gesamtscores (MID = 27)

Protocol: CA209648 Page 1 of 1

FACT-E: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
FACT-E (MID=27)		
EVENT:	32/156 (20.5%)	21/140 (15.0%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	1/ 32 (3.1%)	3/ 21 (14.3%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	17/ 32 (53.1%)	16/ 21 (76.2%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	14/ 32 (43.8%)	2/ 21 (9.5%)
CENSORED:	124/156 (79.5%)	119/140 (85.0%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	19/124 (15.3%)	15/119 (12.6%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	105/124 (84.7%)	104/119 (87.4%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:28:44

3.15 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Gesamtscores (MID = 3, 7, 17)

Protocol: CA209648 Page 1 of 2

FACT-G: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
FACT-G (MID=3)		
EVENT:	86/156 (55.1%)	70/140 (50.0%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	3/ 86 (3.5%)	4/ 70 (5.7%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	26/ 86 (30.2%)	26/ 70 (37.1%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	57/ 86 (66.3%)	40/ 70 (57.1%)
CENSORED:	70/156 (44.9%)	70/140 (50.0%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	31/ 70 (44.3%)	33/ 70 (47.1%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	39/ 70 (55.7%)	37/ 70 (52.9%)
FACT-G (MID=7)		
EVENT:	73/156 (46.8%)	57/140 (40.7%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	1/ 73 (1.4%)	5/ 57 (8.8%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	32/ 73 (43.8%)	28/ 57 (49.1%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	40/ 73 (54.8%)	24/ 57 (42.1%)
CENSORED:	83/156 (53.2%)	83/140 (59.3%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	28/ 83 (33.7%)	34/ 83 (41.0%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	55/ 83 (66.3%)	49/ 83 (59.0%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:28:35

Protocol: CA209648 Page 2 of 2

FACT-G: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
FACT-G (MID=17)		
EVENT:	34/156 (21.8%)	29/140 (20.7%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	0/ 34	2/ 29 (6.9%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	20/ 34 (58.8%)	16/ 29 (55.2%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	14/ 34 (41.2%)	11/ 29 (37.9%)
CENSORED:	122/156 (78.2%)	111/140 (79.3%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	26/122 (21.3%)	11/111 (9.9%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	96/122 (78.7%)	100/111 (90.1%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:28:35

3.16 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala PWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 2

PWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
PWB (MID=2)		
EVENT:	74/156 (47.4%)	78/141 (55.3%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	1/ 74 (1.4%)	2/ 78 (2.6%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	27/ 74 (36.5%)	26/ 78 (33.3%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	46/ 74 (62.2%)	50/ 78 (64.1%)
CENSORED:	82/156 (52.6%)	63/141 (44.7%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	33/ 82 (40.2%)	32/ 63 (50.8%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	49/ 82 (59.8%)	31/ 63 (49.2%)
PWB (MID=3)		
EVENT:	69/156 (44.2%)	64/141 (45.4%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	2/ 69 (2.9%)	2/ 64 (3.1%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	31/ 69 (44.9%)	23/ 64 (35.9%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	36/ 69 (52.2%)	39/ 64 (60.9%)
CENSORED:	87/156 (55.8%)	77/141 (54.6%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	27/ 87 (31.0%)	37/ 77 (48.1%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	60/ 87 (69.0%)	40/ 77 (51.9%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:30

Protocol: CA209648 Page 2 of 2

PWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
PWB (MID=5)		
EVENT:	47/156 (30.1%)	46/141 (32.6%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	2/ 47 (4.3%)	2/ 46 (4.3%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	21/ 47 (44.7%)	20/ 46 (43.5%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	24/ 47 (51.1%)	24/ 46 (52.2%)
CENSORED:	109/156 (69.9%)	95/141 (67.4%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	30/109 (27.5%)	27/ 95 (28.4%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	79/109 (72.5%)	68/ 95 (71.6%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:30

3.17 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala SWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 2

SWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
SWB (MID=2)		
EVENT:	63/156 (40.4%)	48/141 (34.0%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	3/ 63 (4.8%)	3/ 48 (6.3%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	22/ 63 (34.9%)	14/ 48 (29.2%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	38/ 63 (60.3%)	31/ 48 (64.6%)
CENSORED:	93/156 (59.6%)	93/141 (66.0%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	40/ 93 (43.0%)	30/ 93 (32.3%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	53/ 93 (57.0%)	63/ 93 (67.7%)
SWB (MID=3)		
EVENT:	46/156 (29.5%)	43/141 (30.5%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	1/ 46 (2.2%)	2/ 43 (4.7%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	19/ 46 (41.3%)	19/ 43 (44.2%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	26/ 46 (56.5%)	22/ 43 (51.2%)
CENSORED:	110/156 (70.5%)	98/141 (69.5%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	44/110 (40.0%)	27/ 98 (27.6%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	66/110 (60.0%)	71/ 98 (72.4%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:37

Protocol: CA209648 Page 2 of 2

SWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
SWB (MID=5)		
EVENT:	28/156 (17.9%)	23/141 (16.3%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	0/ 28	1/ 23 (4.3%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	15/ 28 (53.6%)	10/ 23 (43.5%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	13/ 28 (46.4%)	12/ 23 (52.2%)
CENSORED:	128/156 (82.1%)	118/141 (83.7%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	30/128 (23.4%)	24/118 (20.3%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	98/128 (76.6%)	94/118 (79.7%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:37

3.18 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala EWB (MID = 2, 3, 4)

Protocol: CA209648 Page 1 of 2

EWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
EWB (MID=2)		
EVENT:	48/156 (30.8%)	53/141 (37.6%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	2/ 48 (4.2%)	4/ 53 (7.5%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	33/ 48 (68.8%)	24/ 53 (45.3%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	13/ 48 (27.1%)	25/ 53 (47.2%)
CENSORED:	108/156 (69.2%)	88/141 (62.4%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	36/108 (33.3%)	30/ 88 (34.1%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	72/108 (66.7%)	58/ 88 (65.9%)
EWB (MID=3)		
EVENT:	35/156 (22.4%)	37/141 (26.2%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	1/ 35 (2.9%)	3/ 37 (8.1%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	24/ 35 (68.6%)	20/ 37 (54.1%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	10/ 35 (28.6%)	14/ 37 (37.8%)
CENSORED:	121/156 (77.6%)	104/141 (73.8%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	35/121 (28.9%)	25/104 (24.0%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	86/121 (71.1%)	79/104 (76.0%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:45

Protocol: CA209648 Page 2 of 2

EWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
EWB (MID=4)		
EVENT:	27/156 (17.3%)	27/141 (19.1%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	2/ 27 (7.4%)	2/ 27 (7.4%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	21/ 27 (77.8%)	15/ 27 (55.6%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	4/ 27 (14.8%)	10/ 27 (37.0%)
CENSORED:	129/156 (82.7%)	114/141 (80.9%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	27/129 (20.9%)	16/114 (14.0%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	102/129 (79.1%)	98/114 (86.0%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:45

3.19 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G Subskala FWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 2

FWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
FWB (MID=2)		
EVENT:	84/156 (53.8%)	63/140 (45.0%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	4/ 84 (4.8%)	2/ 63 (3.2%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	28/ 84 (33.3%)	31/ 63 (49.2%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	52/ 84 (61.9%)	30/ 63 (47.6%)
CENSORED:	72/156 (46.2%)	77/140 (55.0%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	21/ 72 (29.2%)	31/ 77 (40.3%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	51/ 72 (70.8%)	46/ 77 (59.7%)
FWB (MID=3)		
EVENT:	76/156 (48.7%)	55/140 (39.3%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	4/ 76 (5.3%)	2/ 55 (3.6%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	29/ 76 (38.2%)	28/ 55 (50.9%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	43/ 76 (56.6%)	25/ 55 (45.5%)
CENSORED:	80/156 (51.3%)	85/140 (60.7%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	24/ 80 (30.0%)	28/ 85 (32.9%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	56/ 80 (70.0%)	57/ 85 (67.1%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:21

Protocol: CA209648 Page 2 of 2

FWB: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
FWB (MID=5)		
EVENT:	58/156 (37.2%)	39/140 (27.9%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	3/ 58 (5.2%)	3/ 39 (7.7%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	24/ 58 (41.4%)	23/ 39 (59.0%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	31/ 58 (53.4%)	13/ 39 (33.3%)
CENSORED:	98/156 (62.8%)	101/140 (72.1%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	21/ 98 (21.4%)	21/101 (20.8%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	77/ 98 (78.6%)	80/101 (79.2%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:21

3.20 Zusatzanalyse – Art der Ereignisse und Zensierungen – ECS (MID = 11)

Protocol: CA209648 Page 1 of 1

FACT-ECS: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
FACT-ECS (MID=11)		
EVENT:	34/156 (21.8%)	30/142 (21.1%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	1/ 34 (2.9%)	2/ 30 (6.7%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	15/ 34 (44.1%)	20/ 30 (66.7%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	18/ 34 (52.9%)	8/ 30 (26.7%)
CENSORED:	122/156 (78.2%)	112/142 (78.9%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	21/122 (17.2%)	21/112 (18.8%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	101/122 (82.8%)	91/112 (81.3%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:28:58

3.21 Zusatzanalyse – Art der Ereignisse und Zensierungen – FACT-G7 Gesamtscores (MID = 5)

Protocol: CA209648 Page 1 of 1

FACT-G7: Time to Definitive Deterioration Event/Censored Types
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Domains	Nivo + Ipi	Chemotherapy
FACT-G7 (MID=5)		
EVENT:	52/156 (33.3%)	39/141 (27.7%)
PATIENTS WITH A SINGLE DETERIORATION AND NO DATA AFTERWARDS	2/ 52 (3.8%)	2/ 39 (5.1%)
PATIENTS WITH A SINGLE DETERIORATION FOLLOWED BY DEATH	30/ 52 (57.7%)	26/ 39 (66.7%)
PATIENTS WITH DETERIORATION EVENTS OCCURRING AT 2 OR MORE TIME POINTS	20/ 52 (38.5%)	11/ 39 (28.2%)
CENSORED:	104/156 (66.7%)	102/141 (72.3%)
PATIENTS WITH DETERIORATION AND LATER IMPROVEMENT (CENSORED AT LAST PRO ASSESSMENT)	25/104 (24.0%)	27/102 (26.5%)
PATIENTS WITH NO DETERIORATION (CENSORED AT LAST PRO ASSESSMENT OR AT RANDOMIZATION DATE)	79/104 (76.0%)	75/102 (73.5%)

Oct 2021 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-ttdevc-ebr503.sas 07APR2022:09:29:08

3.22 Subgruppenanalysen – FACT-E Gesamtscore (MID = 27)

Protocol: CA209648 Page 1 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	32 (20.5)	N.A. (24.94, N.A.)	140	21 (15.0)	N.A. (11.43, N.A.)	1.008 (0.571, 1.781) 0.8640	
AGE								0.4427
< 65	93	16 (17.2)	N.A. (25.07, N.A.)	74	13 (17.6)	N.A. (9.76, N.A.)	0.700 (0.329, 1.490) 0.5266	
>= 65 AND < 75	55	13 (23.6)	N.A. (19.02, N.A.)	54	7 (13.0)	N.A. (9.00, N.A.)	1.648 (0.646, 4.206) 0.3294	
>= 75	8	3 (37.5)	24.94 (1.61, N.A.)	12	1 (8.3)	N.A. (6.01, N.A.)	1.884 (0.134, 26.431) 0.7316	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:08:19

Protocol: CA209648 Page 2 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9298
MALE	129	30 (23.3)	N.A. (19.02, N.A.)	120	20 (16.7)	N.A. (9.76, N.A.)	0.995 (0.553, 1.791) 0.8896	
FEMALE	27	2 (7.4)	N.A.	20	1 (5.0)	N.A. (9.00, N.A.)	1.597 (0.140, 18.198) 0.7181	
RACE								0.6537
ASIAN	117	29 (24.8)	25.07 (19.02, N.A.)	103	20 (19.4)	N.A. (9.00, N.A.)	0.979 (0.542, 1.769) 0.9962	
NON-ASIAN	39	3 (7.7)	N.A.	37	1 (2.7)	N.A.	2.893 (0.293, 28.543) 0.3417	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:08:19

Protocol: CA209648 Page 3 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.7204
J/K/T	91	22 (24.2)	25.07 (19.02, N.A.)	84	15 (17.9)	N.A. (8.67, N.A.)	1.012 (0.509, 2.012) 0.8520	
REST OF ASIA	25	6 (24.0)	12.68 (5.52, N.A.)	19	5 (26.3)	9.76 (3.38, N.A.)	0.613 (0.171, 2.198) 0.4698	
REST OF WORLD	40	4 (10.0)	N.A.	37	1 (2.7)	N.A.	2.896 (0.304, 27.572) 0.2821	
REGION								0.4884
ASIA	116	28 (24.1)	25.07 (19.02, N.A.)	103	20 (19.4)	N.A. (9.00, N.A.)	0.956 (0.526, 1.737) 0.9280	
NON-ASIA	40	4 (10.0)	N.A.	37	1 (2.7)	N.A.	2.896 (0.304, 27.572) 0.2821	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 4 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6665
0	71	18 (25.4)	N.A. (14.72, N.A.)	68	13 (19.1)	N.A. (8.67, N.A.)	0.908 (0.435, 1.896) 0.9452	
1	85	14 (16.5)	N.A. (24.94, N.A.)	70	8 (11.4)	N.A. (9.76, N.A.)	1.118 (0.450, 2.774) 0.8188	
WEIGHT								0.5441
< 60 KG	95	21 (22.1)	N.A. (19.02, N.A.)	74	11 (14.9)	N.A. (9.00, N.A.)	1.135 (0.536, 2.403) 0.6118	
>= 60 KG	61	11 (18.0)	N.A. (25.07, N.A.)	66	10 (15.2)	N.A. (8.54, N.A.)	0.815 (0.332, 2.000) 0.6853	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8758
STAGE I	5	1 (20.0)	N.A. (2.17, N.A.)	5	2 (40.0)	11.43 (8.54, N.A.)	0.374 (0.029, 4.890) 0.5203	
STAGE II	5	2 (40.0)	7.29 (2.76, N.A.)	5	1 (20.0)	N.A. (0.53, N.A.)	2.078 (0.168, 25.694) 0.7834	
STAGE III	31	5 (16.1)	N.A. (24.94, N.A.)	44	5 (11.4)	N.A. (8.67, N.A.)	1.123 (0.300, 4.211) 0.9633	
STAGE IV	114	23 (20.2)	N.A. (19.02, N.A.)	86	13 (15.1)	N.A. (9.00, N.A.)	0.998 (0.493, 2.021) 0.9465	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2205
GX	11	3 (27.3)	N.A. (1.61, N.A.)	14	1 (7.1)	N.A. (8.54, N.A.)	11.087 (0.707,>99.999) 0.1277	
G1	8	1 (12.5)	N.A. (24.94, N.A.)	7	2 (28.6)	8.25 (5.62, N.A.)	<0.001 (<0.001, N.A.) 0.0423	
G2	58	9 (15.5)	N.A. (25.07, N.A.)	46	5 (10.9)	N.A. (11.43, N.A.)	1.060 (0.337, 3.339) 0.8810	
G3	27	9 (33.3)	19.02 (5.52, N.A.)	36	3 (8.3)	N.A. (9.76, N.A.)	2.869 (0.713, 11.552) 0.1723	
NOT OTHERWISE SPECIFIED	50	10 (20.0)	N.A. (8.74, N.A.)	37	10 (27.0)	8.67 (5.78, N.A.)	0.615 (0.255, 1.487) 0.3001	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 7 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.2583
UPPER THORACIC	35	6 (17.1)	N.A. (5.59, N.A.)	24	7 (29.2)	8.25 (5.59, N.A.)	0.378 (0.122, 1.177) 0.1449	
MIDDLE THORACIC	50	11 (22.0)	N.A. (8.74, N.A.)	50	5 (10.0)	N.A. (8.67, N.A.)	1.729 (0.585, 5.109) 0.2045	
LOWER THORACIC	59	12 (20.3)	N.A. (19.02, N.A.)	59	8 (13.6)	N.A. (9.76, N.A.)	0.928 (0.351, 2.450) 0.8673	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	N.A. (1.71, N.A.)	7	1 (14.3)	N.A. (0.53, N.A.)	0.395 (0.022, 7.213) 0.8020	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 8 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5888
RECURRENT - LOCO-REGIONAL	7	2 (28.6)	N.A. (2.76, N.A.)	12	3 (25.0)	N.A. (5.03, N.A.)	0.729 (0.081, 6.546) 0.7681	
RECURRENT - DISTANT	24	5 (20.8)	24.94 (7.13, N.A.)	27	2 (7.4)	11.43 (N.A., N.A.)	3.041 (0.448, 20.625) 0.5504	
DE NOVO METASTATIC	107	19 (17.8)	N.A.	78	11 (14.1)	N.A. (9.00, N.A.)	1.011 (0.471, 2.166) 0.8890	
UNRESECTABLE ADVANCED	18	6 (33.3)	25.07 (5.52, N.A.)	23	5 (21.7)	N.A. (6.01, N.A.)	0.612 (0.161, 2.329) 0.9036	
SMOKING STATUS								0.7439
CURRENT/FORMER	134	28 (20.9)	N.A. (24.94, N.A.)	109	18 (16.5)	N.A. (9.76, N.A.)	0.907 (0.490, 1.679) 0.7797	
NEVER/UNKNOWN	22	4 (18.2)	N.A. (5.52, N.A.)	31	3 (9.7)	N.A. (9.00, N.A.)	1.462 (0.310, 6.899) 0.3595	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 9 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.8195
CURRENT/FORMER	124	27 (21.8)	N.A. (24.94, N.A.)	115	18 (15.7)	N.A. (9.76, N.A.)	1.038 (0.560, 1.924) 0.8185	
NEVER/UNKNOWN	32	5 (15.6)	N.A. (12.68, N.A.)	25	3 (12.0)	N.A. (5.26, N.A.)	0.927 (0.214, 4.019) 0.9521	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.2710
<= 1	79	14 (17.7)	N.A.	67	13 (19.4)	N.A. (8.67, N.A.)	0.751 (0.348, 1.621) 0.4420	
>= 2	77	18 (23.4)	25.07 (19.02, N.A.)	73	8 (11.0)	N.A. (9.00, N.A.)	1.549 (0.650, 3.693) 0.1996	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 10 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2667
< 1 YEAR	128	24 (18.8)	N.A. (25.07, N.A.)	111	17 (15.3)	N.A. (9.00, N.A.)	0.849 (0.445, 1.621) 0.7386	
1 - < 3 YEARS	23	7 (30.4)	24.94 (2.92, N.A.)	20	3 (15.0)	11.43 (5.03, N.A.)	2.114 (0.505, 8.853) 0.4070	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9170
YES	36	6 (16.7)	N.A. (24.94, N.A.)	35	5 (14.3)	N.A. (8.54, N.A.)	1.100 (0.306, 3.949) 0.8285	
NO	120	26 (21.7)	N.A. (19.02, N.A.)	105	16 (15.2)	N.A. (9.00, N.A.)	1.038 (0.545, 1.978) 0.7520	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 11 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1280
YES	24	5 (20.8)	N.A. (7.13, N.A.)	26	1 (3.8)	N.A. (5.03, N.A.)	6.882 (0.748, 63.333) 0.0716	
NO	132	27 (20.5)	N.A. (24.94, N.A.)	114	20 (17.5)	N.A. (9.00, N.A.)	0.820 (0.448, 1.502) 0.6131	
PD-L1 CPS I								0.8527
< 10	51	8 (15.7)	N.A. (25.07, N.A.)	51	6 (11.8)	N.A. (9.76, N.A.)	0.816 (0.271, 2.453) 0.7753	
>= 10	92	19 (20.7)	N.A. (24.94, N.A.)	87	15 (17.2)	N.A. (9.00, N.A.)	0.997 (0.497, 2.001) 0.9729	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 12 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.9701
< 5	28	6 (21.4)	25.07 (5.42, N.A.)	22	4 (18.2)	9.76 (5.03, N.A.)	0.897 (0.235, 3.428) 0.8115	
>= 5	115	21 (18.3)	N.A. (24.94, N.A.)	116	17 (14.7)	N.A. (11.43, N.A.)	0.942 (0.488, 1.816) 0.9247	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.2700
< 10%	54	10 (18.5)	N.A. (25.07, N.A.)	55	9 (16.4)	N.A. (8.67, N.A.)	0.696 (0.271, 1.787) 0.5648	
>= 10%	102	22 (21.6)	N.A. (19.02, N.A.)	85	12 (14.1)	N.A. (11.43, N.A.)	1.239 (0.597, 2.570) 0.5536	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 13 of 13

FACT-E: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-E (MID=27)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2422
< 5%	37	8 (21.6)	N.A. (25.07, N.A.)	39	9 (23.1)	9.76 (8.67, N.A.)	0.656 (0.242, 1.773) 0.4357	
>= 5%	119	24 (20.2)	N.A. (19.02, N.A.)	101	12 (11.9)	N.A. (11.43, N.A.)	1.253 (0.613, 2.561) 0.4478	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:08:19

3.23 Subgruppenanalysen – FACT-G Gesamtscore (MID = 3, 7, 17)

Protocol: CA209648 Page 1 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	86 (55.1)	6.34 (4.44, 12.48)	140	70 (50.0)	7.06 (5.26, 8.94)	0.845 (0.608, 1.174) 0.5269	
AGE								0.1405
< 65	93	52 (55.9)	6.57 (4.17, 12.48)	74	36 (48.6)	8.67 (5.65, 15.01)	0.946 (0.611, 1.465) 0.9711	
>= 65 AND < 75	55	27 (49.1)	12.55 (4.01, N.A.)	54	30 (55.6)	5.68 (4.14, 8.15)	0.638 (0.369, 1.103) 0.1425	
>= 75	8	7 (87.5)	1.72 (0.53, N.A.)	12	4 (33.3)	N.A. (0.72, N.A.)	2.952 (0.544, 16.024) 0.1136	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 2 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1439
MALE	129	76 (58.9)	6.24 (4.01, 9.89)	120	60 (50.0)	7.43 (5.26, 8.94)	0.909 (0.639, 1.294) 0.8679	
FEMALE	27	10 (37.0)	N.A. (4.17, N.A.)	20	10 (50.0)	5.98 (1.02, N.A.)	0.569 (0.228, 1.422) 0.2775	
RACE								0.4195
ASIAN	117	72 (61.5)	5.62 (2.92, 8.08)	103	56 (54.4)	7.06 (4.21, 8.90)	0.915 (0.638, 1.313) 0.7981	
NON-ASIAN	39	14 (35.9)	18.69 (5.36, N.A.)	37	14 (37.8)	15.01 (4.70, N.A.)	0.626 (0.276, 1.421) 0.4288	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 3 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.7631
J/K/T	91	52 (57.1)	6.14 (2.86, 16.39)	84	44 (52.4)	8.15 (4.21, 9.53)	0.867 (0.569, 1.321) 0.6814	
REST OF ASIA	25	19 (76.0)	4.44 (1.77, 7.00)	19	12 (63.2)	5.03 (0.59, N.A.)	0.943 (0.453, 1.964) 0.9173	
REST OF WORLD	40	15 (37.5)	18.69 (5.36, N.A.)	37	14 (37.8)	15.01 (4.70, N.A.)	0.653 (0.293, 1.459) 0.5056	
REGION								0.4824
ASIA	116	71 (61.2)	5.55 (2.92, 8.08)	103	56 (54.4)	7.06 (4.21, 8.90)	0.910 (0.634, 1.308) 0.7726	
NON-ASIA	40	15 (37.5)	18.69 (5.36, N.A.)	37	14 (37.8)	15.01 (4.70, N.A.)	0.653 (0.293, 1.459) 0.5056	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 4 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.2040
0	71	43 (60.6)	6.14 (4.01, 12.55)	68	41 (60.3)	5.98 (2.92, 8.94)	0.612 (0.386, 0.971) 0.2279	
1	85	43 (50.6)	6.34 (3.32, 16.39)	70	28 (40.0)	7.43 (5.65, N.A.)	1.122 (0.683, 1.843) 0.6366	
WEIGHT								0.3509
< 60 KG	95	52 (54.7)	5.65 (2.86, 8.74)	74	35 (47.3)	8.67 (5.03, 10.51)	0.969 (0.621, 1.513) 0.8590	
>= 60 KG	61	34 (55.7)	9.89 (4.24, 18.69)	66	35 (53.0)	5.68 (4.14, 8.94)	0.693 (0.420, 1.143) 0.2314	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.3782
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	4 (80.0)	8.72 (8.15, N.A.)	0.581 (0.104, 3.253) 0.5137	
STAGE II	5	4 (80.0)	2.76 (0.46, N.A.)	5	2 (40.0)	N.A. (0.53, N.A.)	2.166 (0.326, 14.398) 0.5650	
STAGE III	31	17 (54.8)	6.57 (4.17, 23.79)	44	18 (40.9)	10.51 (5.03, 15.67)	0.793 (0.388, 1.621) 0.8761	
STAGE IV	114	62 (54.4)	6.24 (4.01, 12.55)	86	46 (53.5)	5.68 (4.17, 7.43)	0.837 (0.563, 1.244) 0.4526	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8098
GX	11	6 (54.5)	4.91 (0.53, N.A.)	14	8 (57.1)	5.68 (2.96, N.A.)	1.158 (0.251, 5.331) 0.7164	
G1	8	5 (62.5)	3.32 (0.46, N.A.)	7	4 (57.1)	4.70 (4.14, N.A.)	1.447 (0.348, 6.016) 0.6083	
G2	58	34 (58.6)	8.38 (2.86, 16.39)	46	22 (47.8)	8.90 (2.86, 15.01)	0.759 (0.431, 1.336) 0.5254	
G3	27	14 (51.9)	5.62 (0.66, N.A.)	36	15 (41.7)	9.53 (7.06, N.A.)	1.050 (0.488, 2.261) 0.9070	
NOT OTHERWISE SPECIFIED	50	25 (50.0)	6.34 (3.48, N.A.)	37	21 (56.8)	5.26 (2.76, 5.98)	0.678 (0.374, 1.231) 0.2683	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 7 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8713
UPPER THORACIC	35	22 (62.9)	6.14 (1.48, 12.48)	24	12 (50.0)	5.68 (4.17, N.A.)	0.938 (0.450, 1.956) 0.9593	
MIDDLE THORACIC	50	28 (56.0)	4.83 (1.74, 19.45)	50	27 (54.0)	8.54 (5.26, 10.25)	0.868 (0.496, 1.519) 0.7272	
LOWER THORACIC	59	30 (50.8)	7.00 (4.24, 23.79)	59	29 (49.2)	5.68 (3.75, 10.51)	0.773 (0.456, 1.311) 0.4631	
GASTROESOPHAGEAL JUNCTION	11	5 (45.5)	12.68 (0.66, N.A.)	7	2 (28.6)	N.A. (0.53, N.A.)	0.988 (0.168, 5.818) 0.7244	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 8 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3418
RECURRENT - LOCO-REGIONAL	7	4 (57.1)	12.68 (2.76, N.A.)	12	6 (50.0)	8.54 (2.92, N.A.)	0.614 (0.120, 3.134) 0.6035	
RECURRENT - DISTANT	24	14 (58.3)	5.65 (2.10, N.A.)	27	9 (33.3)	10.51 (4.96, N.A.)	2.101 (0.855, 5.158) 0.2876	
DE NOVO METASTATIC	107	57 (53.3)	6.24 (4.01, 15.31)	78	41 (52.6)	5.68 (4.21, 7.43)	0.830 (0.545, 1.262) 0.4484	
UNRESECTABLE ADVANCED	18	11 (61.1)	5.62 (1.45, N.A.)	23	14 (60.9)	5.59 (0.95, 11.14)	0.639 (0.278, 1.467) 0.4313	
SMOKING STATUS								0.4851
CURRENT/FORMER	134	77 (57.5)	6.34 (4.24, 12.48)	109	55 (50.5)	7.06 (4.96, 8.90)	0.829 (0.577, 1.189) 0.5462	
NEVER/UNKNOWN	22	9 (40.9)	5.36 (2.76, N.A.)	31	15 (48.4)	10.25 (2.86, N.A.)	0.785 (0.325, 1.897) 0.6085	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 9 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.3203
CURRENT/FORMER	124	73 (58.9)	6.14 (4.01, 9.89)	115	57 (49.6)	8.15 (5.59, 9.53)	0.871 (0.607, 1.251) 0.8063	
NEVER/UNKNOWN	32	13 (40.6)	16.39 (2.73, N.A.)	25	13 (52.0)	5.65 (3.75, N.A.)	0.699 (0.314, 1.558) 0.3345	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.8920
<= 1	79	43 (54.4)	6.57 (4.83, 15.31)	67	32 (47.8)	8.54 (4.70, 11.14)	0.882 (0.549, 1.416) 0.7094	
>= 2	77	43 (55.8)	5.36 (2.10, 12.55)	73	38 (52.1)	5.98 (4.47, 10.25)	0.832 (0.526, 1.316) 0.6657	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 10 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.0753
< 1 YEAR	128	68 (53.1)	6.57 (4.83, 15.31)	111	57 (51.4)	5.68 (4.47, 8.94)	0.758 (0.524, 1.096) 0.2479	
1 - < 3 YEARS	23	15 (65.2)	2.92 (1.45, 21.16)	20	8 (40.0)	10.51 (1.15, N.A.)	1.445 (0.588, 3.553) 0.3402	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0274*
YES	36	23 (63.9)	5.62 (2.10, 12.68)	35	13 (37.1)	9.53 (5.03, N.A.)	1.694 (0.842, 3.407) 0.1767	
NO	120	63 (52.5)	6.34 (4.44, 15.31)	105	57 (54.3)	5.68 (4.17, 8.67)	0.725 (0.497, 1.060) 0.1557	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 11 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2236
YES	24	13 (54.2)	4.17 (2.17, N.A.)	26	8 (30.8)	N.A. (1.54, N.A.)	1.367 (0.536, 3.490) 0.3900	
NO	132	73 (55.3)	6.57 (4.44, 12.55)	114	62 (54.4)	5.98 (4.96, 8.90)	0.774 (0.544, 1.101) 0.2621	
PD-L1 CPS I								0.4179
< 10	51	27 (52.9)	5.65 (1.48, 25.07)	51	20 (39.2)	7.06 (4.70, N.A.)	1.014 (0.556, 1.850) 0.6760	
>= 10	92	50 (54.3)	7.00 (4.24, 12.68)	87	49 (56.3)	5.98 (4.21, 8.90)	0.755 (0.501, 1.139) 0.2390	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:09:17

Protocol: CA209648 Page 12 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.3682
< 5	28	16 (57.1)	3.48 (0.99, N.A.)	22	9 (40.9)	7.06 (1.45, N.A.)	1.152 (0.494, 2.686) 0.5720	
>= 5	115	61 (53.0)	6.57 (5.36, 15.31)	116	60 (51.7)	5.98 (4.96, 8.94)	0.775 (0.535, 1.124) 0.2559	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9113
< 10%	54	28 (51.9)	8.38 (4.01, 25.07)	55	23 (41.8)	7.06 (5.26, N.A.)	0.801 (0.449, 1.428) 0.8090	
>= 10%	102	58 (56.9)	6.14 (2.92, 9.89)	85	47 (55.3)	5.68 (4.17, 8.94)	0.860 (0.576, 1.283) 0.5469	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 13 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.3505
< 5%	37	21 (56.8)	6.57 (1.74, 25.07)	39	16 (41.0)	7.06 (5.26, N.A.)	1.013 (0.515, 1.993) 0.7280	
>= 5%	119	65 (54.6)	6.14 (4.24, 12.48)	101	54 (53.5)	5.68 (4.17, 8.94)	0.784 (0.537, 1.144) 0.2946	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 14 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	73 (46.8)	11.86 (6.01, 18.69)	140	57 (40.7)	8.90 (6.47, 11.99)	0.859 (0.598, 1.234) 0.5568	
AGE								0.1704
< 65	93	42 (45.2)	11.86 (6.14, 25.07)	74	33 (44.6)	8.90 (5.68, 15.67)	0.779 (0.486, 1.251) 0.3938	
>= 65 AND < 75	55	24 (43.6)	15.34 (4.44, N.A.)	54	22 (40.7)	8.15 (5.68, N.A.)	0.828 (0.451, 1.521) 0.5617	
>= 75	8	7 (87.5)	3.01 (0.53, N.A.)	12	2 (16.7)	N.A. (0.72, N.A.)	3.193 (0.448, 22.776) 0.0401	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 15 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6402
MALE	129	63 (48.8)	10.38 (6.01, 16.39)	120	50 (41.7)	8.67 (5.78, 13.14)	0.857 (0.581, 1.265) 0.5870	
FEMALE	27	10 (37.0)	N.A. (5.13, N.A.)	20	7 (35.0)	9.00 (4.47, N.A.)	0.914 (0.342, 2.441) 0.9031	
RACE								0.7668
ASIAN	117	60 (51.3)	7.13 (5.62, 15.34)	103	47 (45.6)	8.54 (5.72, 11.99)	0.900 (0.606, 1.337) 0.6702	
NON-ASIAN	39	13 (33.3)	18.69 (10.38, N.A.)	37	10 (27.0)	N.A. (5.68, N.A.)	0.696 (0.278, 1.746) 0.7235	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 16 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9854
J/K/T	91	46 (50.5)	8.08 (5.62, 20.83)	84	38 (45.2)	8.67 (5.72, 13.14)	0.859 (0.547, 1.348) 0.6191	
REST OF ASIA	25	13 (52.0)	5.55 (2.89, 12.98)	19	9 (47.4)	7.06 (0.95, N.A.)	0.899 (0.378, 2.136) 0.8354	
REST OF WORLD	40	14 (35.0)	18.69 (5.62, N.A.)	37	10 (27.0)	N.A. (5.68, N.A.)	0.731 (0.297, 1.802) 0.8307	
REGION								0.8645
ASIA	116	59 (50.9)	7.13 (5.55, 15.34)	103	47 (45.6)	8.54 (5.72, 11.99)	0.891 (0.599, 1.326) 0.6332	
NON-ASIA	40	14 (35.0)	18.69 (5.62, N.A.)	37	10 (27.0)	N.A. (5.68, N.A.)	0.731 (0.297, 1.802) 0.8307	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 17 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7187
0	71	40 (56.3)	7.13 (5.55, 15.34)	68	35 (51.5)	8.54 (5.59, 11.99)	0.748 (0.464, 1.204) 0.4676	
1	85	33 (38.8)	12.98 (5.62, N.A.)	70	22 (31.4)	9.86 (5.68, N.A.)	1.023 (0.581, 1.798) 0.9379	
WEIGHT								0.2790
< 60 KG	95	46 (48.4)	6.57 (5.55, 15.34)	74	29 (39.2)	9.00 (5.68, N.A.)	1.012 (0.625, 1.638) 0.7561	
>= 60 KG	61	27 (44.3)	12.68 (6.57, 27.60)	66	28 (42.4)	8.54 (5.68, N.A.)	0.654 (0.372, 1.151) 0.1690	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 18 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.5670
STAGE I	5	2 (40.0)	12.98 (2.17, N.A.)	5	4 (80.0)	8.72 (8.15, N.A.)	0.194 (0.021, 1.807) 0.1106	
STAGE II	5	4 (80.0)	2.76 (0.53, N.A.)	5	2 (40.0)	N.A. (0.53, N.A.)	2.504 (0.316, 19.806) 0.6690	
STAGE III	31	14 (45.2)	12.68 (5.55, 27.60)	44	15 (34.1)	13.14 (5.52, N.A.)	0.824 (0.376, 1.810) 0.8840	
STAGE IV	114	52 (45.6)	11.86 (5.62, 18.69)	86	36 (41.9)	9.00 (5.68, N.A.)	0.864 (0.556, 1.343) 0.5604	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 19 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.7879
GX	11	6 (54.5)	4.91 (0.53, N.A.)	14	6 (42.9)	8.54 (2.96, N.A.)	2.473 (0.549, 11.129) 0.3302	
G1	8	5 (62.5)	4.63 (0.53, N.A.)	7	3 (42.9)	N.A. (4.14, N.A.)	1.434 (0.306, 6.730) 0.5429	
G2	58	26 (44.8)	16.39 (5.36, 23.79)	46	17 (37.0)	10.25 (5.68, N.A.)	0.743 (0.389, 1.421) 0.4588	
G3	27	14 (51.9)	11.86 (2.89, N.A.)	36	12 (33.3)	11.99 (7.06, N.A.)	1.198 (0.531, 2.704) 0.6705	
NOT OTHERWISE SPECIFIED	50	20 (40.0)	7.13 (5.62, N.A.)	37	19 (51.4)	5.78 (5.03, 9.00)	0.659 (0.348, 1.249) 0.1765	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 20 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9356
UPPER THORACIC	35	19 (54.3)	8.08 (2.92, 27.60)	24	12 (50.0)	5.68 (4.96, 9.00)	0.743 (0.348, 1.586) 0.4687	
MIDDLE THORACIC	50	22 (44.0)	10.38 (5.55, 25.07)	50	22 (44.0)	8.90 (5.68, 13.14)	0.737 (0.393, 1.382) 0.4613	
LOWER THORACIC	59	26 (44.1)	12.98 (5.36, N.A.)	59	21 (35.6)	11.99 (5.72, N.A.)	0.965 (0.532, 1.753) 0.9592	
GASTROESOPHAGEAL JUNCTION	11	5 (45.5)	12.68 (0.66, N.A.)	7	2 (28.6)	N.A. (0.53, N.A.)	0.988 (0.168, 5.818) 0.7244	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 21 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5236
RECURRENT - LOCO-REGIONAL	7	4 (57.1)	12.68 (2.76, N.A.)	12	5 (41.7)	10.27 (5.03, N.A.)	0.688 (0.122, 3.871) 0.8374	
RECURRENT - DISTANT	24	12 (50.0)	7.13 (2.10, N.A.)	27	8 (29.6)	N.A. (4.96, N.A.)	1.673 (0.630, 4.445) 0.5568	
DE NOVO METASTATIC	107	47 (43.9)	10.38 (5.62, 20.83)	78	33 (42.3)	9.00 (5.68, 10.25)	0.823 (0.518, 1.309) 0.4751	
UNRESECTABLE ADVANCED	18	10 (55.6)	11.86 (2.76, N.A.)	23	11 (47.8)	8.67 (3.75, N.A.)	0.676 (0.273, 1.672) 0.4703	
SMOKING STATUS								0.6918
CURRENT/FORMER	134	65 (48.5)	10.38 (6.14, 16.39)	109	46 (42.2)	8.54 (5.68, 11.99)	0.831 (0.559, 1.233) 0.4887	
NEVER/UNKNOWN	22	8 (36.4)	N.A. (4.11, N.A.)	31	11 (35.5)	10.25 (5.59, N.A.)	0.932 (0.353, 2.462) 0.9090	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 22 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.6134
CURRENT/FORMER	124	62 (50.0)	8.08 (5.62, 15.34)	115	48 (41.7)	8.67 (5.78, 13.14)	0.877 (0.592, 1.300) 0.7288	
NEVER/UNKNOWN	32	11 (34.4)	16.39 (5.55, N.A.)	25	9 (36.0)	9.00 (4.96, N.A.)	0.817 (0.325, 2.052) 0.6102	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.7274
<= 1	79	36 (45.6)	12.68 (6.01, 23.79)	67	28 (41.8)	8.90 (6.47, 13.14)	0.788 (0.471, 1.319) 0.4275	
>= 2	77	37 (48.1)	8.74 (4.24, 25.07)	73	29 (39.7)	9.00 (5.52, N.A.)	0.977 (0.587, 1.626) 0.9137	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:09:17

Protocol: CA209648 Page 23 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.1017
< 1 YEAR	128	57 (44.5)	11.86 (6.14, 20.83)	111	46 (41.4)	9.00 (5.72, 13.14)	0.773 (0.515, 1.161) 0.3091	
1 - < 3 YEARS	23	13 (56.5)	7.13 (2.76, 23.79)	20	6 (30.0)	N.A. (1.15, N.A.)	1.618 (0.586, 4.473) 0.2988	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.1688
YES	36	19 (52.8)	12.68 (4.63, 23.79)	35	12 (34.3)	11.99 (6.47, N.A.)	1.276 (0.602, 2.706) 0.5797	
NO	120	54 (45.0)	11.86 (6.01, 25.07)	105	45 (42.9)	8.67 (5.68, 13.14)	0.781 (0.515, 1.185) 0.3200	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 24 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1590
YES	24	13 (54.2)	5.65 (2.17, 23.79)	26	7 (26.9)	N.A. (5.03, N.A.)	1.663 (0.641, 4.312) 0.2825	
NO	132	60 (45.5)	12.48 (6.34, 18.69)	114	50 (43.9)	8.90 (5.78, 11.99)	0.762 (0.515, 1.128) 0.2502	
PD-L1 CPS I								0.1185
< 10	51	26 (51.0)	6.57 (3.48, 25.07)	51	15 (29.4)	13.14 (5.68, N.A.)	1.229 (0.635, 2.379) 0.3463	
>= 10	92	39 (42.4)	12.68 (6.01, 23.79)	87	41 (47.1)	8.67 (5.68, 10.25)	0.696 (0.440, 1.103) 0.1329	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 25 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.1817
< 5	28	15 (53.6)	4.63 (1.45, N.A.)	22	7 (31.8)	7.06 (1.94, N.A.)	1.620 (0.644, 4.075) 0.2693	
>= 5	115	50 (43.5)	12.48 (6.34, 23.79)	116	49 (42.2)	8.90 (5.78, 13.14)	0.751 (0.497, 1.133) 0.2090	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9425
< 10%	54	24 (44.4)	20.83 (5.13, N.A.)	55	20 (36.4)	8.67 (5.68, N.A.)	0.741 (0.397, 1.383) 0.6537	
>= 10%	102	49 (48.0)	8.74 (5.62, 15.34)	85	37 (43.5)	8.90 (5.68, 13.14)	0.879 (0.562, 1.375) 0.6027	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 26 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=7)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.3976
< 5%	37	20 (54.1)	10.38 (2.89, 25.07)	39	15 (38.5)	9.00 (5.26, N.A.)	0.936 (0.464, 1.888) 0.8386	
>= 5%	119	53 (44.5)	11.86 (5.65, 18.69)	101	42 (41.6)	8.90 (5.68, 13.14)	0.814 (0.533, 1.244) 0.3750	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 27 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	34 (21.8)	N.A. (18.69, N.A.)	140	29 (20.7)	15.67 (9.00, N.A.)	0.714 (0.426, 1.197) 0.3107	
AGE								0.4625
< 65	93	16 (17.2)	N.A. (25.07, N.A.)	74	16 (21.6)	15.67 (8.90, N.A.)	0.536 (0.261, 1.097) 0.1743	
>= 65 AND < 75	55	12 (21.8)	N.A. (15.34, N.A.)	54	11 (20.4)	N.A. (8.15, N.A.)	0.776 (0.328, 1.837) 0.5704	
>= 75	8	6 (75.0)	8.23 (0.53, N.A.)	12	2 (16.7)	N.A. (5.55, N.A.)	0.870 (0.097, 7.808) 0.2838	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 28 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9384
MALE	129	30 (23.3)	25.07 (18.69, N.A.)	120	26 (21.7)	15.67 (8.90, N.A.)	0.705 (0.407, 1.222) 0.3615	
FEMALE	27	4 (14.8)	N.A.	20	3 (15.0)	12.88 (8.64, N.A.)	1.053 (0.230, 4.812) 0.8998	
RACE								0.6939
ASIAN	117	28 (23.9)	25.07 (12.68, N.A.)	103	24 (23.3)	12.88 (8.67, N.A.)	0.731 (0.414, 1.290) 0.3434	
NON-ASIAN	39	6 (15.4)	N.A. (18.69, N.A.)	37	5 (13.5)	N.A.	0.749 (0.201, 2.784) 0.9221	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 29 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9810
J/K/T	91	21 (23.1)	25.07 (15.34, N.A.)	84	19 (22.6)	12.88 (8.64, N.A.)	0.689 (0.358, 1.326) 0.3950	
REST OF ASIA	25	6 (24.0)	12.68 (5.52, N.A.)	19	5 (26.3)	9.76 (3.38, N.A.)	0.629 (0.177, 2.232) 0.4698	
REST OF WORLD	40	7 (17.5)	N.A. (18.69, N.A.)	37	5 (13.5)	N.A.	0.792 (0.224, 2.806) 0.9934	
REGION								0.8639
ASIA	116	27 (23.3)	25.07 (15.34, N.A.)	103	24 (23.3)	12.88 (8.67, N.A.)	0.710 (0.400, 1.261) 0.2983	
NON-ASIA	40	7 (17.5)	N.A. (18.69, N.A.)	37	5 (13.5)	N.A.	0.792 (0.224, 2.806) 0.9934	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 30 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6849
0	71	21 (29.6)	22.57 (11.10, N.A.)	68	17 (25.0)	12.88 (8.64, N.A.)	0.740 (0.382, 1.435) 0.6631	
1	85	13 (15.3)	N.A. (18.69, N.A.)	70	12 (17.1)	N.A. (8.90, N.A.)	0.679 (0.297, 1.554) 0.3759	
WEIGHT								0.4369
< 60 KG	95	23 (24.2)	22.57 (11.10, N.A.)	74	16 (21.6)	12.88 (8.90, N.A.)	0.786 (0.406, 1.522) 0.6443	
>= 60 KG	61	11 (18.0)	N.A. (25.07, N.A.)	66	13 (19.7)	N.A. (8.54, N.A.)	0.591 (0.253, 1.378) 0.2745	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 31 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.4864
STAGE I	5	1 (20.0)	N.A. (2.17, N.A.)	5	3 (60.0)	8.72 (8.15, N.A.)	0.304 (0.031, 2.952) 0.2739	
STAGE II	5	3 (60.0)	3.84 (0.53, N.A.)	5	2 (40.0)	N.A. (0.53, N.A.)	2.016 (0.261, 15.578) 0.9880	
STAGE III	31	4 (12.9)	N.A. (9.79, N.A.)	44	6 (13.6)	15.67 (15.67, N.A.)	0.661 (0.180, 2.429) 0.6680	
STAGE IV	114	25 (21.9)	25.07 (15.34, N.A.)	86	18 (20.9)	12.88 (9.00, N.A.)	0.685 (0.362, 1.296) 0.2965	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 32 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8594
GX	11	3 (27.3)	N.A. (1.61, N.A.)	14	2 (14.3)	N.A. (8.54, N.A.)	2.818 (0.315, 25.183) 0.2803	
G1	8	2 (25.0)	N.A. (2.83, N.A.)	7	1 (14.3)	N.A. (5.42, N.A.)	2.584 (0.231, 28.906) 0.4192	
G2	58	11 (19.0)	25.07 (18.69, N.A.)	46	6 (13.0)	N.A. (8.90, N.A.)	0.795 (0.276, 2.290) 0.8030	
G3	27	7 (25.9)	N.A. (8.38, N.A.)	36	8 (22.2)	15.67 (8.64, N.A.)	0.635 (0.210, 1.921) 0.4238	
NOT OTHERWISE SPECIFIED	50	10 (20.0)	N.A. (9.79, N.A.)	37	12 (32.4)	8.67 (5.59, N.A.)	0.532 (0.228, 1.240) 0.1326	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 33 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.1397
UPPER THORACIC	35	6 (17.1)	N.A. (9.79, N.A.)	24	8 (33.3)	8.15 (5.03, N.A.)	0.271 (0.085, 0.866) 0.0452	
MIDDLE THORACIC	50	13 (26.0)	22.57 (18.69, N.A.)	50	7 (14.0)	15.67 (8.67, N.A.)	1.202 (0.449, 3.215) 0.5799	
LOWER THORACIC	59	12 (20.3)	N.A. (12.68, N.A.)	59	12 (20.3)	N.A. (8.64, N.A.)	0.684 (0.295, 1.590) 0.4118	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	N.A. (1.71, N.A.)	7	2 (28.6)	N.A. (0.53, N.A.)	0.235 (0.019, 2.862) 0.7155	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:09:17

Protocol: CA209648 Page 34 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.7743
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (2.76, N.A.)	12	3 (25.0)	N.A. (5.03, N.A.)	0.679 (0.059, 7.789) 0.6954	
RECURRENT - DISTANT	24	4 (16.7)	N.A. (9.79, N.A.)	27	4 (14.8)	N.A. (8.90, N.A.)	2.234 (0.453, 11.018) 0.9291	
DE NOVO METASTATIC	107	23 (21.5)	N.A. (15.34, N.A.)	78	16 (20.5)	12.88 (8.64, N.A.)	0.689 (0.353, 1.344) 0.3552	
UNRESECTABLE ADVANCED	18	6 (33.3)	25.07 (5.52, N.A.)	23	6 (26.1)	15.67 (5.55, N.A.)	0.665 (0.198, 2.235) 0.6248	
SMOKING STATUS								0.9048
CURRENT/FORMER	134	30 (22.4)	25.07 (18.69, N.A.)	109	24 (22.0)	15.67 (8.64, N.A.)	0.677 (0.385, 1.190) 0.2327	
NEVER/UNKNOWN	22	4 (18.2)	N.A. (5.52, N.A.)	31	5 (16.1)	12.88 (9.00, N.A.)	1.070 (0.267, 4.288) 0.9196	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 35 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.9355
CURRENT/FORMER	124	28 (22.6)	25.07 (18.69, N.A.)	115	25 (21.7)	12.88 (8.67, N.A.)	0.677 (0.385, 1.190) 0.2786	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (12.68, N.A.)	25	4 (16.0)	N.A. (5.26, N.A.)	1.019 (0.281, 3.699) 0.9873	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.2476
<= 1	79	15 (19.0)	N.A. (18.69, N.A.)	67	17 (25.4)	15.67 (8.64, N.A.)	0.488 (0.233, 1.022) 0.0689	
>= 2	77	19 (24.7)	25.07 (11.10, N.A.)	73	12 (16.4)	12.88 (9.00, N.A.)	1.098 (0.516, 2.336) 0.6364	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 36 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2125
< 1 YEAR	128	26 (20.3)	N.A. (18.69, N.A.)	111	23 (20.7)	12.88 (9.00, N.A.)	0.564 (0.311, 1.023) 0.1157	
1 - < 3 YEARS	23	7 (30.4)	9.79 (2.83, N.A.)	20	4 (20.0)	N.A. (5.03, N.A.)	1.710 (0.495, 5.907) 0.3591	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.7318
YES	36	5 (13.9)	N.A.	35	7 (20.0)	N.A. (8.54, N.A.)	0.717 (0.225, 2.281) 0.4940	
NO	120	29 (24.2)	25.07 (15.34, N.A.)	105	22 (21.0)	12.88 (9.00, N.A.)	0.737 (0.411, 1.324) 0.4461	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 37 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1845
YES	24	6 (25.0)	N.A. (3.84, N.A.)	26	3 (11.5)	N.A. (8.15, N.A.)	2.174 (0.540, 8.754) 0.2379	
NO	132	28 (21.2)	N.A. (18.69, N.A.)	114	26 (22.8)	12.88 (8.90, N.A.)	0.587 (0.334, 1.030) 0.1098	
PD-L1 CPS I								0.1021
< 10	51	11 (21.6)	22.57 (22.57, N.A.)	51	5 (9.8)	N.A. (9.76, N.A.)	1.171 (0.383, 3.583) 0.4832	
>= 10	92	17 (18.5)	N.A. (18.69, N.A.)	87	24 (27.6)	12.88 (8.64, N.A.)	0.518 (0.271, 0.988) 0.0524	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 38 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.3013
< 5	28	7 (25.0)	22.57 (5.42, N.A.)	22	4 (18.2)	9.76 (5.03, N.A.)	1.031 (0.276, 3.852) 0.9848	
>= 5	115	21 (18.3)	N.A.	116	25 (21.6)	15.67 (8.90, N.A.)	0.597 (0.329, 1.085) 0.1319	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.8444
< 10%	54	11 (20.4)	25.07 (22.57, N.A.)	55	10 (18.2)	9.76 (8.67, N.A.)	0.560 (0.224, 1.399) 0.3714	
>= 10%	102	23 (22.5)	N.A. (15.34, N.A.)	85	19 (22.4)	12.88 (8.90, N.A.)	0.762 (0.403, 1.439) 0.4757	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 39 of 39

FACT-G: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G (MID=17)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7647
< 5%	37	10 (27.0)	25.07 (22.57, N.A.)	39	9 (23.1)	9.76 (8.67, N.A.)	0.722 (0.277, 1.881) 0.6634	
>= 5%	119	24 (20.2)	N.A. (15.34, N.A.)	101	20 (19.8)	12.88 (8.90, N.A.)	0.694 (0.373, 1.292) 0.3318	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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3.24 Subgruppenanalysen – FACT-G Subskala PWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	74 (47.4)	9.95 (6.11, 16.39)	141	78 (55.3)	5.59 (4.21, 6.80)	0.622 (0.448, 0.864) 0.0053	
AGE								0.5675
< 65	93	43 (46.2)	7.00 (5.13, 21.16)	74	39 (52.7)	6.34 (2.96, 11.14)	0.697 (0.448, 1.085) 0.1078	
>= 65 AND < 75	55	27 (49.1)	10.38 (4.24, 16.39)	55	31 (56.4)	5.39 (4.14, 6.47)	0.593 (0.344, 1.023) 0.0644	
>= 75	8	4 (50.0)	19.45 (0.66, N.A.)	12	8 (66.7)	5.55 (0.59, N.A.)	0.322 (0.083, 1.258) 0.1000	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:33:49

Protocol: CA209648 Page 2 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9059
MALE	129	63 (48.8)	10.38 (5.52, 16.39)	121	69 (57.0)	5.59 (4.17, 6.80)	0.603 (0.422, 0.860) 0.0054	
FEMALE	27	11 (40.7)	6.11 (5.13, N.A.)	20	9 (45.0)	5.55 (1.48, N.A.)	0.777 (0.321, 1.881) 0.5956	
RACE								0.7577
ASIAN	117	58 (49.6)	7.00 (5.55, 13.93)	103	62 (60.2)	5.39 (3.35, 6.34)	0.602 (0.416, 0.870) 0.0053	
NON-ASIAN	39	16 (41.0)	18.69 (5.13, N.A.)	38	16 (42.1)	6.93 (4.17, N.A.)	0.655 (0.309, 1.387) 0.4007	

Oct 2021 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.
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(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 3 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.3292
J/K/T	91	43 (47.3)	12.48 (5.09, 25.07)	84	54 (64.3)	4.70 (2.92, 6.18)	0.541 (0.357, 0.820) 0.0021	
REST OF ASIA	25	14 (56.0)	6.24 (2.76, 9.89)	19	8 (42.1)	7.06 (0.95, N.A.)	1.041 (0.428, 2.531) 0.8618	
REST OF WORLD	40	17 (42.5)	13.54 (5.13, N.A.)	38	16 (42.1)	6.93 (4.17, N.A.)	0.639 (0.304, 1.345) 0.3757	
REGION								0.7468
ASIA	116	57 (49.1)	7.00 (5.52, 13.93)	103	62 (60.2)	5.39 (3.35, 6.34)	0.609 (0.421, 0.881) 0.0065	
NON-ASIA	40	17 (42.5)	13.54 (5.13, N.A.)	38	16 (42.1)	6.93 (4.17, N.A.)	0.639 (0.304, 1.345) 0.3757	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 4 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6821
0	71	38 (53.5)	9.95 (5.09, 13.93)	68	41 (60.3)	5.55 (2.89, 7.92)	0.658 (0.419, 1.032) 0.0567	
1	85	36 (42.4)	10.38 (5.36, 25.07)	71	37 (52.1)	5.55 (4.17, 7.06)	0.592 (0.365, 0.961) 0.0357	
WEIGHT								0.5214
< 60 KG	95	42 (44.2)	9.95 (5.55, 19.45)	74	42 (56.8)	5.03 (2.92, 8.44)	0.561 (0.361, 0.872) 0.0106	
>= 60 KG	61	32 (52.5)	9.89 (4.30, 21.16)	67	36 (53.7)	5.65 (4.21, 6.93)	0.702 (0.427, 1.155) 0.1827	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.7523
STAGE I	5	3 (60.0)	7.00 (0.99, N.A.)	5	4 (80.0)	0.64 (0.62, N.A.)	0.518 (0.068, 3.937) 0.0371	
STAGE II	5	2 (40.0)	N.A. (2.76, N.A.)	5	2 (40.0)	1.48 (0.53, N.A.)	0.341 (0.028, 4.109) 0.3332	
STAGE III	31	16 (51.6)	6.57 (3.71, N.A.)	45	25 (55.6)	6.47 (3.35, 13.14)	0.811 (0.422, 1.557) 0.3353	
STAGE IV	114	52 (45.6)	12.48 (6.11, 18.69)	86	47 (54.7)	5.59 (4.14, 6.93)	0.591 (0.391, 0.895) 0.0196	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8980
GX	11	7 (63.6)	2.14 (0.53, N.A.)	14	11 (78.6)	3.10 (0.99, 6.34)	0.847 (0.311, 2.305) 0.9992	
G1	8	5 (62.5)	4.63 (0.53, N.A.)	7	4 (57.1)	4.70 (1.51, N.A.)	1.028 (0.238, 4.440) 0.9521	
G2	58	25 (43.1)	16.39 (6.24, 25.07)	47	25 (53.2)	4.70 (1.64, 11.14)	0.477 (0.268, 0.847) 0.0138	
G3	27	13 (48.1)	13.54 (4.30, N.A.)	36	19 (52.8)	7.06 (4.24, N.A.)	0.593 (0.274, 1.287) 0.1683	
NOT OTHERWISE SPECIFIED	50	22 (44.0)	6.57 (4.37, N.A.)	37	19 (51.4)	5.65 (3.38, N.A.)	0.736 (0.395, 1.373) 0.3235	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:33:49

Protocol: CA209648 Page 7 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7320
UPPER THORACIC	35	19 (54.3)	6.57 (2.96, 16.39)	24	11 (45.8)	5.59 (1.51, N.A.)	0.787 (0.353, 1.751) 0.6626	
MIDDLE THORACIC	50	26 (52.0)	6.24 (2.79, 19.45)	50	29 (58.0)	5.39 (2.89, 11.14)	0.700 (0.402, 1.219) 0.2494	
LOWER THORACIC	59	23 (39.0)	12.68 (5.52, N.A.)	59	32 (54.2)	5.72 (4.14, 7.92)	0.509 (0.293, 0.885) 0.0104	
GASTROESOPHAGEAL JUNCTION	11	5 (45.5)	12.68 (0.56, N.A.)	8	6 (75.0)	6.34 (0.53, N.A.)	0.379 (0.092, 1.564) 0.1250	

Oct 2021 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.
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(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 8 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.6283
RECURRENT - LOCO-REGIONAL	7	5 (71.4)	12.68 (0.56, N.A.)	12	6 (50.0)	6.80 (0.62, N.A.)	0.839 (0.226, 3.106) 0.8697	
RECURRENT - DISTANT	24	11 (45.8)	6.57 (2.96, N.A.)	27	13 (48.1)	7.92 (1.48, 10.51)	1.128 (0.469, 2.712) 0.6552	
DE NOVO METASTATIC	107	47 (43.9)	10.38 (6.11, 18.69)	78	42 (53.8)	5.55 (3.38, 6.93)	0.582 (0.376, 0.902) 0.0253	
UNRESECTABLE ADVANCED	18	11 (61.1)	6.34 (3.84, 25.07)	24	17 (70.8)	5.39 (1.51, 11.14)	0.532 (0.239, 1.186) 0.1111	
SMOKING STATUS								0.6916
CURRENT/FORMER	134	65 (48.5)	10.38 (6.14, 16.39)	109	64 (58.7)	5.39 (3.38, 6.18)	0.563 (0.393, 0.807) 0.0014	
NEVER/UNKNOWN	22	9 (40.9)	5.55 (2.86, N.A.)	32	14 (43.8)	6.47 (4.14, N.A.)	0.805 (0.337, 1.921) 0.8425	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 9 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.8894
CURRENT/FORMER	124	60 (48.4)	9.89 (5.55, 13.93)	116	65 (56.0)	5.55 (4.17, 6.80)	0.631 (0.439, 0.907) 0.0092	
NEVER/UNKNOWN	32	14 (43.8)	12.68 (3.71, N.A.)	25	13 (52.0)	5.65 (2.96, N.A.)	0.616 (0.272, 1.396) 0.3410	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4921
<= 1	79	35 (44.3)	12.68 (6.14, 19.45)	68	41 (60.3)	5.55 (3.35, 7.06)	0.536 (0.336, 0.855) 0.0046	
>= 2	77	39 (50.6)	9.89 (3.71, 16.39)	73	37 (50.7)	5.68 (4.17, 8.64)	0.731 (0.457, 1.168) 0.2936	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 10 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.1092
< 1 YEAR	128	59 (46.1)	10.38 (6.11, 18.69)	112	64 (57.1)	5.55 (4.14, 6.34)	0.544 (0.376, 0.787) 0.0026	
1 - < 3 YEARS	23	13 (56.5)	3.84 (2.79, 21.16)	20	9 (45.0)	7.92 (1.64, N.A.)	1.209 (0.499, 2.932) 0.8647	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4695
YES	36	20 (55.6)	7.00 (2.96, 16.39)	36	21 (58.3)	5.03 (1.51, 8.44)	0.869 (0.449, 1.682) 0.2348	
NO	120	54 (45.0)	10.38 (6.11, 19.45)	105	57 (54.3)	5.59 (4.17, 6.93)	0.590 (0.399, 0.871) 0.0144	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 11 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1733
YES	24	10 (41.7)	5.55 (2.92, N.A.)	26	8 (30.8)	N.A. (1.48, N.A.)	1.156 (0.443, 3.014) 0.8140	
NO	132	64 (48.5)	9.95 (6.11, 13.93)	115	70 (60.9)	5.55 (3.75, 6.34)	0.555 (0.390, 0.789) 0.0015	
PD-L1 CPS I								0.1646
< 10	51	26 (51.0)	6.57 (3.71, 25.07)	51	21 (41.2)	6.93 (4.70, 7.92)	0.862 (0.475, 1.565) 0.7438	
>= 10	92	43 (46.7)	9.95 (5.55, 18.69)	88	56 (63.6)	4.24 (2.96, 5.72)	0.534 (0.354, 0.807) 0.0022	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 12 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.2269
< 5	28	14 (50.0)	5.13 (2.86, N.A.)	22	8 (36.4)	7.06 (2.86, N.A.)	1.110 (0.447, 2.758) 0.7465	
>= 5	115	55 (47.8)	9.95 (6.11, 16.39)	117	69 (59.0)	5.55 (3.38, 6.34)	0.585 (0.406, 0.841) 0.0037	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.1525
< 10%	54	29 (53.7)	6.11 (3.71, 25.07)	55	23 (41.8)	6.18 (4.24, N.A.)	0.873 (0.492, 1.550) 0.9481	
>= 10%	102	45 (44.1)	12.48 (6.14, 18.69)	86	55 (64.0)	5.39 (3.35, 6.34)	0.493 (0.325, 0.747) 0.0004	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 13 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.0498*
< 5%	37	22 (59.5)	6.57 (2.96, 19.45)	39	16 (41.0)	6.93 (4.24, N.A.)	1.036 (0.528, 2.034) 0.6905	
>= 5%	119	52 (43.7)	12.48 (6.14, 18.69)	102	62 (60.8)	5.39 (3.35, 6.18)	0.506 (0.344, 0.743) 0.0003	

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(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 14 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	69 (44.2)	12.68 (6.57, 18.50)	141	64 (45.4)	6.47 (5.59, 8.64)	0.673 (0.472, 0.960) 0.0311	
AGE								0.8966
< 65	93	40 (43.0)	9.89 (6.34, 25.07)	74	33 (44.6)	8.64 (3.75, 15.67)	0.738 (0.461, 1.181) 0.1991	
>= 65 AND < 75	55	25 (45.5)	13.93 (5.52, 18.69)	55	26 (47.3)	5.72 (5.03, 8.44)	0.601 (0.330, 1.094) 0.0948	
>= 75	8	4 (50.0)	19.45 (0.66, N.A.)	12	5 (41.7)	8.44 (3.35, N.A.)	0.579 (0.129, 2.599) 0.4822	

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(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 15 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6061
MALE	129	58 (45.0)	12.68 (7.13, 18.50)	121	57 (47.1)	6.18 (5.55, 8.44)	0.634 (0.431, 0.931) 0.0203	
FEMALE	27	11 (40.7)	6.11 (5.13, N.A.)	20	7 (35.0)	12.88 (2.83, N.A.)	0.966 (0.365, 2.557) 0.9590	
RACE								0.5907
ASIAN	117	53 (45.3)	12.48 (6.57, 16.39)	103	52 (50.5)	5.72 (5.03, 8.44)	0.641 (0.430, 0.954) 0.0250	
NON-ASIAN	39	16 (41.0)	18.50 (5.36, N.A.)	38	12 (31.6)	8.64 (5.65, N.A.)	0.759 (0.334, 1.725) 0.6231	

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(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 16 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.3348
J/K/T	91	39 (42.9)	14.72 (6.57, 25.07)	84	45 (53.6)	5.68 (4.70, 8.44)	0.567 (0.361, 0.890) 0.0100	
REST OF ASIA	25	13 (52.0)	6.34 (2.86, 12.68)	19	7 (36.8)	7.06 (0.95, N.A.)	1.108 (0.431, 2.848) 0.7732	
REST OF WORLD	40	17 (42.5)	13.54 (5.52, 27.60)	38	12 (31.6)	8.64 (5.65, N.A.)	0.744 (0.330, 1.680) 0.6001	
REGION								0.5620
ASIA	116	52 (44.8)	12.48 (6.34, 16.62)	103	52 (50.5)	5.72 (5.03, 8.44)	0.648 (0.435, 0.966) 0.0288	
NON-ASIA	40	17 (42.5)	13.54 (5.52, 27.60)	38	12 (31.6)	8.64 (5.65, N.A.)	0.744 (0.330, 1.680) 0.6001	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 17 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6919
0	71	36 (50.7)	12.48 (6.08, 16.62)	68	34 (50.0)	6.47 (5.39, 12.88)	0.700 (0.433, 1.134) 0.1397	
1	85	33 (38.8)	13.54 (6.34, 25.07)	71	30 (42.3)	6.18 (4.70, 11.14)	0.646 (0.380, 1.097) 0.1014	
WEIGHT								0.9720
< 60 KG	95	39 (41.1)	13.54 (6.34, 19.45)	74	33 (44.6)	8.44 (4.70, 12.88)	0.670 (0.414, 1.083) 0.1047	
>= 60 KG	61	30 (49.2)	12.48 (5.52, 25.07)	67	31 (46.3)	6.18 (5.55, 7.06)	0.667 (0.391, 1.138) 0.1510	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:33:49

Protocol: CA209648 Page 18 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.2278
STAGE I	5	2 (40.0)	N.A. (0.99, N.A.)	5	4 (80.0)	0.97 (0.62, N.A.)	0.094 (0.004, 2.196) 0.0231	
STAGE II	5	2 (40.0)	N.A. (2.76, N.A.)	5	2 (40.0)	2.83 (0.53, N.A.)	0.463 (0.040, 5.331) 0.4593	
STAGE III	31	16 (51.6)	12.68 (3.71, N.A.)	45	17 (37.8)	8.44 (5.39, N.A.)	1.094 (0.530, 2.260) 0.9460	
STAGE IV	114	48 (42.1)	13.54 (6.57, 18.69)	86	41 (47.7)	5.72 (4.70, 11.14)	0.588 (0.379, 0.915) 0.0258	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 19 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9538
GX	11	7 (63.6)	3.29 (0.53, N.A.)	14	9 (64.3)	4.42 (1.48, N.A.)	1.182 (0.422, 3.306) 0.6592	
G1	8	4 (50.0)	8.71 (0.99, N.A.)	7	3 (42.9)	N.A. (1.51, N.A.)	1.233 (0.204, 7.455) 0.9717	
G2	58	24 (41.4)	16.39 (6.24, 25.07)	47	21 (44.7)	6.47 (2.79, 12.88)	0.554 (0.302, 1.016) 0.0736	
G3	27	13 (48.1)	13.93 (5.42, 27.60)	36	14 (38.9)	8.44 (6.80, N.A.)	0.629 (0.263, 1.504) 0.2861	
NOT OTHERWISE SPECIFIED	50	19 (38.0)	12.48 (6.11, N.A.)	37	17 (45.9)	5.65 (3.75, N.A.)	0.640 (0.325, 1.260) 0.1970	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 20 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7768
UPPER THORACIC	35	16 (45.7)	12.48 (6.57, 27.60)	24	11 (45.8)	5.59 (1.51, N.A.)	0.578 (0.250, 1.335) 0.1987	
MIDDLE THORACIC	50	24 (48.0)	10.38 (4.17, 25.07)	50	23 (46.0)	8.64 (4.70, N.A.)	0.813 (0.447, 1.480) 0.5450	
LOWER THORACIC	59	23 (39.0)	14.72 (6.34, N.A.)	59	26 (44.1)	6.80 (5.55, N.A.)	0.624 (0.347, 1.124) 0.0953	
GASTROESOPHAGEAL JUNCTION	11	5 (45.5)	12.68 (0.56, N.A.)	8	4 (50.0)	6.47 (0.53, N.A.)	0.490 (0.105, 2.273) 0.3406	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 21 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.4769
RECURRENT - LOCO-REGIONAL	7	5 (71.4)	12.68 (0.56, N.A.)	12	5 (41.7)	6.80 (0.62, N.A.)	1.062 (0.272, 4.153) 0.8666	
RECURRENT - DISTANT	24	10 (41.7)	8.71 (3.71, N.A.)	27	9 (33.3)	8.44 (6.47, N.A.)	1.168 (0.443, 3.075) 0.8253	
DE NOVO METASTATIC	107	43 (40.2)	12.68 (6.24, 19.45)	78	38 (48.7)	5.68 (4.70, 8.64)	0.569 (0.360, 0.902) 0.0244	
UNRESECTABLE ADVANCED	18	11 (61.1)	13.54 (3.84, 25.07)	24	12 (50.0)	5.59 (3.35, N.A.)	0.576 (0.232, 1.429) 0.2296	
SMOKING STATUS								0.3983
CURRENT/FORMER	134	60 (44.8)	12.68 (8.71, 18.50)	109	53 (48.6)	5.68 (5.03, 8.44)	0.582 (0.393, 0.860) 0.0059	
NEVER/UNKNOWN	22	9 (40.9)	5.55 (5.13, N.A.)	32	11 (34.4)	11.14 (5.59, N.A.)	1.079 (0.436, 2.668) 0.7759	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 22 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.6393
CURRENT/FORMER	124	57 (46.0)	12.48 (6.34, 18.50)	116	53 (45.7)	6.47 (5.55, 8.64)	0.699 (0.473, 1.033) 0.0597	
NEVER/UNKNOWN	32	12 (37.5)	12.68 (5.52, N.A.)	25	11 (44.0)	11.14 (3.38, N.A.)	0.650 (0.270, 1.568) 0.3098	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.5536
<= 1	79	33 (41.8)	13.54 (7.13, 18.69)	68	32 (47.1)	6.18 (5.39, 11.14)	0.552 (0.330, 0.923) 0.0167	
>= 2	77	36 (46.8)	10.38 (5.13, 25.07)	73	32 (43.8)	6.93 (5.03, 12.88)	0.808 (0.492, 1.327) 0.4937	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 23 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.0212*
< 1 YEAR	128	54 (42.2)	13.54 (6.57, 18.69)	112	54 (48.2)	5.72 (5.55, 8.44)	0.550 (0.369, 0.820) 0.0053	
1 - < 3 YEARS	23	13 (56.5)	3.84 (2.79, 27.60)	20	5 (25.0)	N.A. (5.03, N.A.)	2.267 (0.779, 6.591) 0.1754	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.2538
YES	36	19 (52.8)	8.71 (4.21, 16.39)	36	15 (41.7)	8.44 (5.03, N.A.)	1.051 (0.512, 2.158) 0.7966	
NO	120	50 (41.7)	13.93 (7.13, 19.45)	105	49 (46.7)	5.72 (5.55, 11.14)	0.594 (0.391, 0.903) 0.0228	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 24 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.3453
YES	24	10 (41.7)	7.13 (2.92, N.A.)	26	8 (30.8)	N.A. (2.83, N.A.)	1.107 (0.424, 2.889) 0.8714	
NO	132	59 (44.7)	12.68 (6.57, 18.50)	115	56 (48.7)	6.18 (5.55, 8.64)	0.611 (0.416, 0.897) 0.0144	
PD-L1 CPS I								0.1842
< 10	51	25 (49.0)	6.57 (5.13, 19.45)	51	17 (33.3)	7.06 (5.03, N.A.)	0.942 (0.496, 1.789) 0.9390	
>= 10	92	39 (42.4)	12.68 (8.71, 18.69)	88	46 (52.3)	5.68 (4.70, 11.14)	0.563 (0.359, 0.882) 0.0104	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 25 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.4361
< 5	28	13 (46.4)	5.42 (3.55, N.A.)	22	8 (36.4)	7.06 (2.86, N.A.)	0.961 (0.382, 2.418) 0.9799	
>= 5	115	51 (44.3)	12.68 (7.13, 18.50)	117	55 (47.0)	6.18 (5.55, 11.14)	0.637 (0.429, 0.946) 0.0257	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5588
< 10%	54	26 (48.1)	7.13 (5.52, 25.07)	55	21 (38.2)	7.06 (5.03, N.A.)	0.732 (0.399, 1.346) 0.5266	
>= 10%	102	43 (42.2)	12.68 (8.71, 18.69)	86	43 (50.0)	5.72 (5.39, 11.14)	0.592 (0.377, 0.931) 0.0176	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 26 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2253
< 5%	37	20 (54.1)	6.57 (5.42, 19.45)	39	15 (38.5)	7.06 (5.03, N.A.)	0.886 (0.436, 1.800) 0.9156	
>= 5%	119	49 (41.2)	12.68 (8.71, 18.69)	102	49 (48.0)	5.72 (5.39, 8.64)	0.590 (0.389, 0.896) 0.0109	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 27 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	47 (30.1)	21.22 (12.48, N.A.)	141	46 (32.6)	8.90 (8.15, N.A.)	0.658 (0.432, 1.003) 0.0502	
AGE								0.5390
< 65	93	30 (32.3)	25.07 (8.71, N.A.)	74	23 (31.1)	12.88 (8.64, N.A.)	0.822 (0.474, 1.427) 0.4768	
>= 65 AND < 75	55	14 (25.5)	21.22 (10.38, N.A.)	55	19 (34.5)	8.15 (5.59, N.A.)	0.495 (0.238, 1.030) 0.0547	
>= 75	8	3 (37.5)	N.A. (0.66, N.A.)	12	4 (33.3)	8.44 (4.70, N.A.)	0.363 (0.062, 2.130) 0.2716	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 28 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7584
MALE	129	40 (31.0)	25.07 (10.38, N.A.)	121	41 (33.9)	8.64 (7.62, N.A.)	0.642 (0.408, 1.011) 0.0508	
FEMALE	27	7 (25.9)	21.22 (5.36, N.A.)	20	5 (25.0)	12.88 (5.55, N.A.)	0.684 (0.205, 2.281) 0.6781	
RACE								0.5534
ASIAN	117	40 (34.2)	16.39 (8.74, N.A.)	103	38 (36.9)	8.90 (6.80, 15.67)	0.675 (0.425, 1.072) 0.0821	
NON-ASIAN	39	7 (17.9)	N.A.	38	8 (21.1)	N.A. (5.65, N.A.)	0.608 (0.208, 1.781) 0.4645	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:33:49

Protocol: CA209648 Page 29 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4678
J/K/T	91	30 (33.0)	21.22 (9.07, N.A.)	84	33 (39.3)	8.44 (5.78, 15.67)	0.617 (0.366, 1.041) 0.0511	
REST OF ASIA	25	10 (40.0)	8.71 (5.52, 12.68)	19	5 (26.3)	9.76 (3.38, N.A.)	1.094 (0.363, 3.300) 0.8462	
REST OF WORLD	40	7 (17.5)	N.A.	38	8 (21.1)	N.A. (5.65, N.A.)	0.581 (0.198, 1.710) 0.4154	
REGION								0.4759
ASIA	116	40 (34.5)	16.39 (8.74, N.A.)	103	38 (36.9)	8.90 (6.80, 15.67)	0.687 (0.433, 1.092) 0.0957	
NON-ASIA	40	7 (17.5)	N.A.	38	8 (21.1)	N.A. (5.65, N.A.)	0.581 (0.198, 1.710) 0.4154	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 30 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6164
0	71	28 (39.4)	12.68 (8.08, N.A.)	68	27 (39.7)	8.44 (5.59, N.A.)	0.715 (0.415, 1.230) 0.1885	
1	85	19 (22.4)	N.A. (16.39, N.A.)	71	19 (26.8)	8.90 (8.44, N.A.)	0.588 (0.300, 1.155) 0.1177	
WEIGHT								0.8962
< 60 KG	95	28 (29.5)	20.83 (8.74, N.A.)	74	26 (35.1)	8.90 (8.44, N.A.)	0.609 (0.349, 1.063) 0.0796	
>= 60 KG	61	19 (31.1)	25.07 (9.89, N.A.)	67	20 (29.9)	9.76 (5.78, N.A.)	0.688 (0.357, 1.328) 0.2620	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:33:49

Protocol: CA209648 Page 31 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.7543
STAGE I	5	2 (40.0)	N.A. (0.99, N.A.)	5	4 (80.0)	7.47 (0.62, N.A.)	0.205 (0.016, 2.603) 0.1316	
STAGE II	5	0	N.E.	5	1 (20.0)	N.A. (0.53, N.A.)	N.E. 0.2636	
STAGE III	31	10 (32.3)	N.A. (6.34, N.A.)	45	12 (26.7)	15.67 (8.44, N.A.)	1.127 (0.479, 2.651) 0.9438	
STAGE IV	114	34 (29.8)	21.22 (10.38, N.A.)	86	29 (33.7)	9.76 (5.78, N.A.)	0.581 (0.344, 0.983) 0.0543	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 32 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.6687
GX	11	5 (45.5)	8.08 (0.66, N.A.)	14	4 (28.6)	N.A. (2.83, N.A.)	1.566 (0.412, 5.960) 0.3934	
G1	8	2 (25.0)	N.A. (0.99, N.A.)	7	3 (42.9)	N.A. (4.14, N.A.)	0.430 (0.040, 4.671) 0.3633	
G2	58	18 (31.0)	20.83 (9.89, N.A.)	47	13 (27.7)	12.88 (8.15, N.A.)	0.718 (0.343, 1.500) 0.4065	
G3	27	6 (22.2)	N.A. (5.52, N.A.)	36	13 (36.1)	9.76 (6.80, N.A.)	0.398 (0.139, 1.139) 0.0787	
NOT OTHERWISE SPECIFIED	50	15 (30.0)	12.48 (7.03, N.A.)	37	13 (35.1)	7.62 (5.26, N.A.)	0.604 (0.279, 1.312) 0.2057	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 33 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8398
UPPER THORACIC	35	11 (31.4)	16.39 (8.51, N.A.)	24	9 (37.5)	8.15 (3.38, N.A.)	0.564 (0.224, 1.419) 0.1800	
MIDDLE THORACIC	50	17 (34.0)	20.83 (7.03, N.A.)	50	17 (34.0)	12.88 (5.39, N.A.)	0.735 (0.364, 1.486) 0.4323	
LOWER THORACIC	59	17 (28.8)	N.A. (8.71, N.A.)	59	18 (30.5)	9.76 (6.80, N.A.)	0.740 (0.370, 1.482) 0.2992	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A. (1.22, N.A.)	8	2 (25.0)	N.A. (0.53, N.A.)	0.783 (0.102, 5.992) 0.9290	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 34 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3135
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (2.86, N.A.)	12	5 (41.7)	8.15 (2.92, N.A.)	0.362 (0.042, 3.140) 0.2962	
RECURRENT - DISTANT	24	8 (33.3)	8.71 (3.71, N.A.)	27	6 (22.2)	8.90 (8.44, N.A.)	1.619 (0.519, 5.054) 0.4953	
DE NOVO METASTATIC	107	32 (29.9)	20.83 (9.89, N.A.)	78	27 (34.6)	9.76 (5.78, N.A.)	0.564 (0.328, 0.969) 0.0534	
UNRESECTABLE ADVANCED	18	6 (33.3)	25.07 (5.52, N.A.)	24	8 (33.3)	15.67 (4.17, N.A.)	0.495 (0.152, 1.612) 0.2871	
SMOKING STATUS								0.5985
CURRENT/FORMER	134	41 (30.6)	21.22 (10.38, N.A.)	109	38 (34.9)	8.44 (6.80, 15.67)	0.582 (0.366, 0.925) 0.0173	
NEVER/UNKNOWN	22	6 (27.3)	N.A. (5.13, N.A.)	32	8 (25.0)	12.88 (12.88, N.A.)	0.898 (0.303, 2.662) 0.9708	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 35 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.7203
CURRENT/FORMER	124	38 (30.6)	21.22 (9.89, N.A.)	116	38 (32.8)	8.90 (7.62, 15.67)	0.681 (0.427, 1.086) 0.0781	
NEVER/UNKNOWN	32	9 (28.1)	16.39 (8.71, N.A.)	25	8 (32.0)	N.A. (4.70, N.A.)	0.655 (0.232, 1.851) 0.4006	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.1583
<= 1	79	18 (22.8)	N.A. (12.68, N.A.)	68	24 (35.3)	8.90 (5.65, N.A.)	0.437 (0.229, 0.835) 0.0052	
>= 2	77	29 (37.7)	12.48 (6.11, N.A.)	73	22 (30.1)	12.88 (8.15, N.A.)	0.955 (0.538, 1.695) 0.9629	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 36 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2143
< 1 YEAR	128	38 (29.7)	21.22 (12.48, N.A.)	112	37 (33.0)	9.76 (5.78, 15.67)	0.557 (0.345, 0.899) 0.0236	
1 - < 3 YEARS	23	7 (30.4)	N.A. (2.92, N.A.)	20	5 (25.0)	N.A. (5.03, N.A.)	1.571 (0.478, 5.166) 0.6101	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9255
YES	36	9 (25.0)	N.A. (8.71, N.A.)	36	12 (33.3)	8.44 (6.80, N.A.)	0.682 (0.271, 1.718) 0.2367	
NO	120	38 (31.7)	21.22 (9.89, N.A.)	105	34 (32.4)	9.76 (5.78, N.A.)	0.665 (0.409, 1.082) 0.1402	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 37 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.7238
YES	24	5 (20.8)	N.A. (8.51, N.A.)	26	6 (23.1)	N.A. (5.03, N.A.)	0.935 (0.281, 3.111) 0.8118	
NO	132	42 (31.8)	21.22 (10.38, N.A.)	115	40 (34.8)	8.90 (6.80, 15.67)	0.615 (0.390, 0.968) 0.0394	
PD-L1 CPS I								0.4112
< 10	51	18 (35.3)	20.83 (6.11, N.A.)	51	13 (25.5)	9.76 (5.26, N.A.)	0.842 (0.396, 1.788) 0.7595	
>= 10	92	26 (28.3)	21.22 (9.89, N.A.)	88	32 (36.4)	8.90 (7.62, N.A.)	0.584 (0.341, 1.002) 0.0404	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 38 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.4539
< 5	28	11 (39.3)	20.83 (3.55, N.A.)	22	7 (31.8)	8.44 (5.03, N.A.)	0.917 (0.338, 2.487) 0.8843	
>= 5	115	33 (28.7)	N.A. (10.38, N.A.)	117	38 (32.5)	12.88 (7.62, N.A.)	0.627 (0.388, 1.013) 0.0526	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5142
< 10%	54	17 (31.5)	20.83 (8.51, N.A.)	55	13 (23.6)	9.76 (8.44, N.A.)	0.743 (0.344, 1.608) 0.6807	
>= 10%	102	30 (29.4)	21.22 (9.07, N.A.)	86	33 (38.4)	8.64 (5.78, N.A.)	0.592 (0.352, 0.994) 0.0328	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 39 of 39

PWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: PWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2805
< 5%	37	15 (40.5)	20.83 (6.11, N.A.)	39	11 (28.2)	9.76 (5.65, N.A.)	0.931 (0.407, 2.133) 0.9821	
>= 5%	119	32 (26.9)	N.A. (9.89, N.A.)	102	35 (34.3)	8.90 (6.80, N.A.)	0.573 (0.348, 0.944) 0.0204	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:33:49

3.25 Subgruppenanalysen – FACT-G Subskala SWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	63 (40.4)	16.39 (8.74, 21.98)	141	48 (34.0)	11.14 (7.98, N.A.)	0.838 (0.567, 1.239) 0.6788	
AGE								0.1373
< 65	93	38 (40.9)	20.76 (6.34, N.A.)	74	24 (32.4)	15.01 (8.67, N.A.)	0.953 (0.562, 1.618) 0.9084	
>= 65 AND < 75	55	20 (36.4)	10.38 (5.65, 18.00)	55	22 (40.0)	7.98 (4.14, N.A.)	0.550 (0.290, 1.046) 0.1365	
>= 75	8	5 (62.5)	4.14 (0.56, N.A.)	12	2 (16.7)	N.A. (1.41, N.A.)	3.433 (0.652, 18.086) 0.0939	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 2 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2315
MALE	129	53 (41.1)	13.50 (6.97, 21.98)	121	39 (32.2)	18.76 (8.67, N.A.)	0.933 (0.607, 1.433) 0.9537	
FEMALE	27	10 (37.0)	18.00 (3.78, N.A.)	20	9 (45.0)	7.98 (1.15, N.A.)	0.514 (0.200, 1.318) 0.2108	
RACE								0.5061
ASIAN	117	49 (41.9)	12.42 (6.01, 18.00)	103	35 (34.0)	11.14 (7.98, N.A.)	0.896 (0.572, 1.405) 0.9946	
NON-ASIAN	39	14 (35.9)	21.98 (4.17, N.A.)	38	13 (34.2)	15.01 (3.29, N.A.)	0.709 (0.319, 1.578) 0.5072	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 3 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.8498
J/K/T	91	39 (42.9)	13.50 (5.65, 20.76)	84	29 (34.5)	11.14 (6.93, N.A.)	0.817 (0.492, 1.357) 0.9533	
REST OF ASIA	25	9 (36.0)	8.74 (2.76, N.A.)	19	6 (31.6)	N.A. (0.99, N.A.)	0.945 (0.331, 2.695) 0.9483	
REST OF WORLD	40	15 (37.5)	21.98 (4.17, N.A.)	38	13 (34.2)	15.01 (3.29, N.A.)	0.744 (0.340, 1.625) 0.5702	
REGION								0.5900
ASIA	116	48 (41.4)	12.42 (6.34, 18.00)	103	35 (34.0)	11.14 (7.98, N.A.)	0.885 (0.563, 1.390) 0.9471	
NON-ASIA	40	15 (37.5)	21.98 (4.17, N.A.)	38	13 (34.2)	15.01 (3.29, N.A.)	0.744 (0.340, 1.625) 0.5702	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 4 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.2211
0	71	33 (46.5)	13.50 (5.65, 27.60)	68	28 (41.2)	10.25 (4.93, N.A.)	0.594 (0.344, 1.026) 0.4550	
1	85	30 (35.3)	16.39 (8.74, N.A.)	71	19 (26.8)	15.01 (6.34, N.A.)	1.083 (0.597, 1.966) 0.7944	
WEIGHT								0.1309
< 60 KG	95	42 (44.2)	9.23 (5.62, 18.00)	74	25 (33.8)	10.25 (6.93, N.A.)	1.013 (0.608, 1.688) 0.7664	
>= 60 KG	61	21 (34.4)	27.60 (10.38, N.A.)	67	23 (34.3)	18.76 (4.21, N.A.)	0.678 (0.364, 1.265) 0.3538	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.5323
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	0	N.E.	N.E. 0.2262	
STAGE II	5	5 (100.0)	3.78 (2.76, N.A.)	5	1 (20.0)	N.A. (0.95, N.A.)	6.823 (0.434,>99.999) 0.3540	
STAGE III	31	12 (38.7)	20.76 (5.55, 27.60)	45	14 (31.1)	11.14 (7.98, N.A.)	0.733 (0.310, 1.736) 0.5885	
STAGE IV	114	43 (37.7)	16.39 (6.97, N.A.)	86	33 (38.4)	10.25 (4.21, N.A.)	0.724 (0.453, 1.157) 0.2915	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.3184
GX	11	3 (27.3)	N.A. (0.53, N.A.)	14	6 (42.9)	6.34 (4.21, N.A.)	0.538 (0.107, 2.704) 0.9880	
G1	8	3 (37.5)	N.A. (0.59, N.A.)	7	1 (14.3)	N.A. (0.92, N.A.)	2.913 (0.288, 29.489) 0.2834	
G2	58	25 (43.1)	16.39 (5.65, 21.98)	47	16 (34.0)	11.14 (4.17, N.A.)	0.773 (0.406, 1.475) 0.6998	
G3	27	10 (37.0)	27.60 (5.42, N.A.)	36	7 (19.4)	N.A.	1.845 (0.686, 4.961) 0.2177	
NOT OTHERWISE SPECIFIED	50	21 (42.0)	9.23 (4.63, N.A.)	37	18 (48.6)	7.98 (1.45, N.A.)	0.545 (0.286, 1.040) 0.0829	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 7 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9208
UPPER THORACIC	35	16 (45.7)	12.42 (5.55, 27.60)	24	8 (33.3)	18.76 (1.54, N.A.)	0.678 (0.266, 1.728) 0.5752	
MIDDLE THORACIC	50	20 (40.0)	10.38 (4.17, N.A.)	50	20 (40.0)	10.25 (5.68, N.A.)	0.985 (0.529, 1.832) 0.9396	
LOWER THORACIC	59	23 (39.0)	18.00 (6.34, N.A.)	59	18 (30.5)	N.A. (4.21, N.A.)	0.876 (0.455, 1.686) 0.9725	
GASTROESOPHAGEAL JUNCTION	11	4 (36.4)	N.A. (0.66, N.A.)	8	2 (25.0)	N.A. (3.29, N.A.)	2.416 (0.381, 15.324) 0.5144	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 8 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.2114
RECURRENT - LOCO-REGIONAL	7	3 (42.9)	27.60 (0.53, N.A.)	12	4 (33.3)	N.A. (1.15, N.A.)	0.195 (0.020, 1.897) 0.9061	
RECURRENT - DISTANT	24	12 (50.0)	9.23 (4.14, 20.76)	27	5 (18.5)	N.A.	1.959 (0.650, 5.903) 0.2611	
DE NOVO METASTATIC	107	40 (37.4)	16.39 (8.74, N.A.)	78	30 (38.5)	10.25 (4.21, N.A.)	0.714 (0.438, 1.166) 0.2761	
UNRESECTABLE ADVANCED	18	8 (44.4)	N.A. (2.76, N.A.)	24	9 (37.5)	11.14 (3.29, N.A.)	0.808 (0.310, 2.106) 0.8490	
SMOKING STATUS								0.1777
CURRENT/FORMER	134	55 (41.0)	13.50 (8.74, 21.98)	109	33 (30.3)	N.A. (8.67, N.A.)	0.937 (0.599, 1.466) 0.8479	
NEVER/UNKNOWN	22	8 (36.4)	N.A. (2.76, N.A.)	32	15 (46.9)	7.98 (3.29, N.A.)	0.610 (0.243, 1.532) 0.3416	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 9 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.8670
CURRENT/FORMER	124	50 (40.3)	13.50 (6.97, 21.98)	116	38 (32.8)	11.14 (7.98, N.A.)	0.804 (0.517, 1.250) 0.7579	
NEVER/UNKNOWN	32	13 (40.6)	16.39 (4.14, N.A.)	25	10 (40.0)	15.01 (1.54, N.A.)	0.835 (0.356, 1.955) 0.6930	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.0695
<= 1	79	33 (41.8)	13.50 (5.65, N.A.)	68	17 (25.0)	N.A. (11.14, N.A.)	1.263 (0.693, 2.300) 0.2627	
>= 2	77	30 (39.0)	16.39 (6.34, 27.60)	73	31 (42.5)	6.93 (4.14, 15.01)	0.605 (0.356, 1.029) 0.1107	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 10 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.1725
< 1 YEAR	128	48 (37.5)	16.99 (9.07, N.A.)	112	41 (36.6)	10.25 (6.34, N.A.)	0.700 (0.453, 1.082) 0.2289	
1 - < 3 YEARS	23	12 (52.2)	5.55 (2.76, 20.76)	20	6 (30.0)	N.A. (1.15, N.A.)	1.324 (0.474, 3.693) 0.5539	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0287*
YES	36	17 (47.2)	16.39 (3.78, 21.98)	36	7 (19.4)	N.A. (7.98, N.A.)	1.823 (0.735, 4.524) 0.1030	
NO	120	46 (38.3)	13.50 (6.97, N.A.)	105	41 (39.0)	10.25 (5.68, N.A.)	0.687 (0.444, 1.064) 0.1655	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 11 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2104
YES	24	16 (66.7)	4.17 (2.76, 20.76)	26	9 (34.6)	N.A. (1.48, N.A.)	1.351 (0.569, 3.206) 0.4218	
NO	132	47 (35.6)	16.99 (9.07, N.A.)	115	39 (33.9)	11.14 (8.67, N.A.)	0.760 (0.490, 1.178) 0.4287	
PD-L1 CPS I								0.6529
< 10	51	19 (37.3)	21.98 (5.65, N.A.)	51	18 (35.3)	11.14 (4.93, N.A.)	0.693 (0.351, 1.369) 0.4550	
>= 10	92	39 (42.4)	16.39 (5.62, 20.76)	88	30 (34.1)	15.01 (6.93, N.A.)	0.896 (0.547, 1.470) 0.9123	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 12 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.7501
< 5	28	10 (35.7)	21.98 (4.14, N.A.)	22	7 (31.8)	N.A. (1.94, N.A.)	0.997 (0.369, 2.691) 0.9755	
>= 5	115	48 (41.7)	16.39 (9.07, 27.60)	117	41 (35.0)	11.14 (7.98, N.A.)	0.806 (0.522, 1.246) 0.5642	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.2975
< 10%	54	21 (38.9)	16.99 (9.23, N.A.)	55	22 (40.0)	15.01 (3.98, N.A.)	0.644 (0.346, 1.197) 0.2168	
>= 10%	102	42 (41.2)	12.42 (5.65, 27.60)	86	26 (30.2)	11.14 (7.98, N.A.)	1.044 (0.627, 1.740) 0.5405	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 13 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.5512
< 5%	37	13 (35.1)	N.A. (6.34, N.A.)	39	15 (38.5)	18.76 (3.98, N.A.)	0.718 (0.336, 1.533) 0.4044	
>= 5%	119	50 (42.0)	13.50 (5.65, 20.76)	102	33 (32.4)	11.14 (6.93, N.A.)	0.888 (0.559, 1.410) 0.9551	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 14 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	46 (29.5)	20.76 (12.42, N.A.)	141	43 (30.5)	15.01 (8.67, N.A.)	0.667 (0.433, 1.029) 0.1654	
AGE								0.1351
< 65	93	28 (30.1)	N.A. (12.42, N.A.)	74	23 (31.1)	15.01 (8.67, N.A.)	0.733 (0.416, 1.293) 0.4291	
>= 65 AND < 75	55	14 (25.5)	18.69 (10.38, N.A.)	55	19 (34.5)	7.98 (5.68, N.A.)	0.409 (0.193, 0.868) 0.0444	
>= 75	8	4 (50.0)	6.01 (0.59, N.A.)	12	1 (8.3)	N.A. (1.41, N.A.)	6.236 (0.608, 63.985) 0.0937	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 15 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0569
MALE	129	41 (31.8)	20.76 (10.38, N.A.)	121	34 (28.1)	18.76 (8.67, N.A.)	0.827 (0.516, 1.324) 0.6926	
FEMALE	27	5 (18.5)	N.A. (18.00, N.A.)	20	9 (45.0)	7.98 (1.54, N.A.)	0.227 (0.069, 0.746) 0.0092	
RACE								0.2881
ASIAN	117	37 (31.6)	18.00 (9.07, N.A.)	103	31 (30.1)	11.14 (8.67, N.A.)	0.759 (0.463, 1.245) 0.4971	
NON-ASIAN	39	9 (23.1)	N.A. (18.69, N.A.)	38	12 (31.6)	15.01 (4.21, N.A.)	0.438 (0.173, 1.104) 0.1313	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 16 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.5340
J/K/T	91	28 (30.8)	20.76 (9.23, N.A.)	84	26 (31.0)	11.14 (8.67, N.A.)	0.646 (0.367, 1.139) 0.3733	
REST OF ASIA	25	8 (32.0)	8.74 (5.52, N.A.)	19	5 (26.3)	N.A. (2.56, N.A.)	1.003 (0.320, 3.148) 0.9497	
REST OF WORLD	40	10 (25.0)	N.A. (10.38, N.A.)	38	12 (31.6)	15.01 (4.21, N.A.)	0.483 (0.198, 1.179) 0.1758	
REGION								0.3820
ASIA	116	36 (31.0)	20.76 (9.23, N.A.)	103	31 (30.1)	11.14 (8.67, N.A.)	0.744 (0.452, 1.224) 0.4476	
NON-ASIA	40	10 (25.0)	N.A. (10.38, N.A.)	38	12 (31.6)	15.01 (4.21, N.A.)	0.483 (0.198, 1.179) 0.1758	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 17 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7439
0	71	25 (35.2)	18.00 (9.07, N.A.)	68	23 (33.8)	11.14 (7.98, N.A.)	0.543 (0.294, 1.006) 0.3215	
1	85	21 (24.7)	N.A. (12.42, N.A.)	71	19 (26.8)	15.01 (6.34, N.A.)	0.754 (0.396, 1.435) 0.3935	
WEIGHT								0.1036
< 60 KG	95	32 (33.7)	18.00 (6.34, N.A.)	74	23 (31.1)	11.14 (7.98, N.A.)	0.852 (0.494, 1.471) 0.7717	
>= 60 KG	61	14 (23.0)	N.A. (18.69, N.A.)	67	20 (29.9)	18.76 (6.54, N.A.)	0.484 (0.232, 1.007) 0.0730	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 18 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.3869
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	0	N.E.	N.E. 0.2262	
STAGE II	5	5 (100.0)	3.78 (2.76, N.A.)	5	1 (20.0)	N.A. (0.95, N.A.)	6.823 (0.434,>99.999) 0.3540	
STAGE III	31	7 (22.6)	N.A. (20.76, N.A.)	45	13 (28.9)	11.14 (7.98, N.A.)	0.529 (0.197, 1.419) 0.2743	
STAGE IV	114	31 (27.2)	N.A. (11.17, N.A.)	86	29 (33.7)	10.25 (6.34, N.A.)	0.549 (0.324, 0.933) 0.0484	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 19 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.1418
GX	11	2 (18.2)	N.A. (0.53, N.A.)	14	5 (35.7)	6.34 (4.21, N.A.)	0.368 (0.056, 2.434) 0.7230	
G1	8	3 (37.5)	N.A. (0.59, N.A.)	7	1 (14.3)	N.A. (4.24, N.A.)	4.115 (0.408, 41.542) 0.1662	
G2	58	15 (25.9)	20.76 (12.42, N.A.)	47	16 (34.0)	11.14 (4.17, N.A.)	0.383 (0.182, 0.805) 0.0345	
G3	27	9 (33.3)	N.A. (5.52, N.A.)	36	5 (13.9)	N.A.	2.393 (0.795, 7.200) 0.1104	
NOT OTHERWISE SPECIFIED	50	16 (32.0)	18.00 (6.01, N.A.)	37	16 (43.2)	6.54 (2.83, N.A.)	0.484 (0.237, 0.990) 0.0574	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 20 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9479
UPPER THORACIC	35	10 (28.6)	N.A. (9.07, N.A.)	24	7 (29.2)	18.76 (1.94, N.A.)	0.493 (0.167, 1.458) 0.3050	
MIDDLE THORACIC	50	16 (32.0)	18.69 (8.74, N.A.)	50	18 (36.0)	11.14 (6.54, N.A.)	0.728 (0.366, 1.451) 0.4328	
LOWER THORACIC	59	18 (30.5)	20.76 (11.17, N.A.)	59	16 (27.1)	N.A. (7.98, N.A.)	0.794 (0.390, 1.617) 0.7371	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A. (2.76, N.A.)	8	2 (25.0)	N.A. (3.29, N.A.)	1.728 (0.166, 17.952) 0.9693	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 21 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.1151
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (2.76, N.A.)	12	4 (33.3)	N.A. (3.06, N.A.)	0.052 (0.003, 0.957) 0.4674	
RECURRENT - DISTANT	24	9 (37.5)	20.76 (4.14, N.A.)	27	4 (14.8)	N.A.	2.144 (0.638, 7.202) 0.2406	
DE NOVO METASTATIC	107	28 (26.2)	N.A. (11.17, N.A.)	78	27 (34.6)	10.25 (5.82, N.A.)	0.498 (0.286, 0.867) 0.0247	
UNRESECTABLE ADVANCED	18	8 (44.4)	N.A. (2.76, N.A.)	24	8 (33.3)	11.14 (6.34, N.A.)	0.968 (0.361, 2.598) 0.9186	
SMOKING STATUS								0.0207*
CURRENT/FORMER	134	43 (32.1)	18.69 (10.38, N.A.)	109	28 (25.7)	N.A. (11.14, N.A.)	0.878 (0.537, 1.436) 0.9303	
NEVER/UNKNOWN	22	3 (13.6)	N.A. (5.52, N.A.)	32	15 (46.9)	7.98 (3.29, 15.01)	0.174 (0.046, 0.663) 0.0090	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 22 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.9207
CURRENT/FORMER	124	36 (29.0)	20.76 (12.42, N.A.)	116	34 (29.3)	18.76 (8.67, N.A.)	0.623 (0.381, 1.020) 0.2015	
NEVER/UNKNOWN	32	10 (31.3)	N.A. (5.52, N.A.)	25	9 (36.0)	15.01 (4.17, N.A.)	0.759 (0.304, 1.893) 0.5533	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.2704
<= 1	79	25 (31.6)	18.69 (9.23, N.A.)	68	17 (25.0)	N.A. (8.67, N.A.)	0.834 (0.438, 1.588) 0.8253	
>= 2	77	21 (27.3)	N.A. (10.38, N.A.)	73	26 (35.6)	10.25 (5.82, N.A.)	0.559 (0.308, 1.016) 0.0928	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 23 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2132
< 1 YEAR	128	34 (26.6)	N.A. (12.42, N.A.)	112	36 (32.1)	11.14 (6.54, N.A.)	0.526 (0.322, 0.861) 0.0282	
1 - < 3 YEARS	23	9 (39.1)	20.76 (2.92, N.A.)	20	6 (30.0)	N.A. (1.15, N.A.)	1.153 (0.398, 3.340) 0.7905	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0480*
YES	36	12 (33.3)	20.76 (5.62, N.A.)	36	6 (16.7)	N.A.	1.538 (0.567, 4.177) 0.2379	
NO	120	34 (28.3)	N.A. (11.17, N.A.)	105	37 (35.2)	10.25 (6.34, N.A.)	0.539 (0.331, 0.876) 0.0231	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 24 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2765
YES	24	11 (45.8)	5.65 (2.86, N.A.)	26	8 (30.8)	N.A. (2.83, N.A.)	1.181 (0.462, 3.017) 0.6062	
NO	132	35 (26.5)	N.A. (12.42, N.A.)	115	35 (30.4)	15.01 (8.67, N.A.)	0.588 (0.361, 0.958) 0.0795	
PD-L1 CPS I								0.9332
< 10	51	13 (25.5)	N.A. (10.38, N.A.)	51	14 (27.5)	11.14 (6.34, N.A.)	0.624 (0.283, 1.379) 0.3982	
>= 10	92	29 (31.5)	18.69 (9.23, N.A.)	88	29 (33.0)	15.01 (7.98, N.A.)	0.663 (0.387, 1.134) 0.2307	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 25 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.1627
< 5	28	8 (28.6)	N.A. (4.14, N.A.)	22	4 (18.2)	N.A.	1.654 (0.495, 5.529) 0.4273	
>= 5	115	34 (29.6)	20.76 (12.42, N.A.)	117	39 (33.3)	11.14 (7.98, N.A.)	0.572 (0.353, 0.929) 0.0577	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.1303
< 10%	54	14 (25.9)	N.A. (10.38, N.A.)	55	21 (38.2)	8.67 (4.17, N.A.)	0.453 (0.227, 0.904) 0.0361	
>= 10%	102	32 (31.4)	18.69 (9.07, N.A.)	86	22 (25.6)	N.A. (10.25, N.A.)	0.915 (0.516, 1.622) 0.9895	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 26 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.6269
< 5%	37	10 (27.0)	N.A. (9.23, N.A.)	39	14 (35.9)	18.76 (6.54, N.A.)	0.547 (0.237, 1.260) 0.1791	
>= 5%	119	36 (30.3)	18.69 (11.17, N.A.)	102	29 (28.4)	15.01 (10.25, N.A.)	0.727 (0.434, 1.215) 0.4075	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 27 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	28 (17.9)	N.A. (19.02, N.A.)	141	23 (16.3)	15.01 (11.14, N.A.)	0.702 (0.393, 1.253) 0.4264	
AGE								0.4383
< 65	93	15 (16.1)	N.A.	74	13 (17.6)	15.01 (10.25, N.A.)	0.612 (0.285, 1.314) 0.3266	
>= 65 AND < 75	55	10 (18.2)	N.A. (18.69, N.A.)	55	9 (16.4)	N.A. (7.98, N.A.)	0.664 (0.252, 1.754) 0.5705	
>= 75	8	3 (37.5)	N.A. (0.59, N.A.)	12	1 (8.3)	N.A. (1.41, N.A.)	5.226 (0.476, 57.366) 0.1701	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 28 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0477*
MALE	129	26 (20.2)	N.A. (18.69, N.A.)	121	17 (14.0)	18.76 (N.A., N.A.)	0.960 (0.506, 1.824) 0.8205	
FEMALE	27	2 (7.4)	N.A.	20	6 (30.0)	10.25 (4.17, N.A.)	0.187 (0.037, 0.939) 0.0240	
RACE								0.3247
ASIAN	117	22 (18.8)	N.A. (19.02, N.A.)	103	16 (15.5)	18.76 (10.25, N.A.)	0.842 (0.430, 1.651) 0.8503	
NON-ASIAN	39	6 (15.4)	N.A. (18.69, N.A.)	38	7 (18.4)	15.01 (15.01, N.A.)	0.422 (0.129, 1.383) 0.2648	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 29 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.2739
J/K/T	91	14 (15.4)	N.A. (19.02, N.A.)	84	14 (16.7)	18.76 (10.25, N.A.)	0.581 (0.263, 1.282) 0.3639	
REST OF ASIA	25	7 (28.0)	12.68 (6.34, N.A.)	19	2 (10.5)	N.A.	2.006 (0.400, 10.070) 0.3754	
REST OF WORLD	40	7 (17.5)	N.A. (18.69, N.A.)	38	7 (18.4)	15.01 (15.01, N.A.)	0.508 (0.165, 1.567) 0.3864	
REGION								0.4651
ASIA	116	21 (18.1)	N.A. (19.02, N.A.)	103	16 (15.5)	18.76 (10.25, N.A.)	0.803 (0.406, 1.588) 0.7445	
NON-ASIA	40	7 (17.5)	N.A. (18.69, N.A.)	38	7 (18.4)	15.01 (15.01, N.A.)	0.508 (0.165, 1.567) 0.3864	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 30 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.8761
0	71	16 (22.5)	N.A. (19.02, N.A.)	68	12 (17.6)	18.76 (10.25, N.A.)	0.671 (0.301, 1.493) 0.8434	
1	85	12 (14.1)	N.A. (18.69, N.A.)	71	10 (14.1)	15.01 (N.A., N.A.)	0.706 (0.290, 1.716) 0.4442	
WEIGHT								0.4698
< 60 KG	95	18 (18.9)	N.A. (19.02, N.A.)	74	13 (17.6)	15.01 (10.25, N.A.)	0.844 (0.408, 1.746) 0.7202	
>= 60 KG	61	10 (16.4)	N.A. (18.69, N.A.)	67	10 (14.9)	18.76 (N.A., N.A.)	0.664 (0.255, 1.726) 0.5109	

Oct 2021 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 31 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.4291
STAGE I	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE II	5	2 (40.0)	4.14 (2.76, N.A.)	5	1 (20.0)	N.A. (0.95, N.A.)	1.332 (0.099, 17.924) 0.9942	
STAGE III	31	3 (9.7)	N.A.	45	10 (22.2)	11.14 (7.98, N.A.)	0.317 (0.084, 1.195) 0.1089	
STAGE IV	114	22 (19.3)	N.A. (18.69, N.A.)	86	12 (14.0)	15.01 (10.25, N.A.)	0.847 (0.404, 1.778) 0.8491	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 32 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.1742
GX	11	1 (9.1)	N.A. (4.17, N.A.)	14	1 (7.1)	N.A.	<0.001 (<0.001, N.A.) 0.5654	
G1	8	1 (12.5)	N.A. (2.83, N.A.)	7	0	N.E.	N.E. 0.2801	
G2	58	9 (15.5)	N.A. (18.69, N.A.)	47	13 (27.7)	15.01 (6.90, N.A.)	0.283 (0.116, 0.689) 0.0124	
G3	27	8 (29.6)	19.02 (5.52, N.A.)	36	2 (5.6)	N.A.	4.388 (0.890, 21.643) 0.0480	
NOT OTHERWISE SPECIFIED	50	8 (16.0)	N.A.	37	7 (18.9)	N.A. (7.98, N.A.)	0.697 (0.250, 1.941) 0.5135	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 33 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7655
UPPER THORACIC	35	5 (14.3)	N.A. (12.42, N.A.)	24	4 (16.7)	18.76 (5.59, N.A.)	0.198 (0.035, 1.131) 0.3761	
MIDDLE THORACIC	50	9 (18.0)	N.A. (10.38, N.A.)	50	12 (24.0)	15.01 (8.67, N.A.)	0.576 (0.234, 1.417) 0.2412	
LOWER THORACIC	59	12 (20.3)	N.A. (19.02, N.A.)	59	7 (11.9)	N.A.	1.308 (0.492, 3.480) 0.5226	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A. (2.76, N.A.)	8	0	N.E.	N.E. 0.1732	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 34 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.6847
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (2.76, N.A.)	12	3 (25.0)	N.A. (4.17, N.A.)	<0.001 (<0.001, N.A.) 0.6443	
RECURRENT - DISTANT	24	3 (12.5)	N.A.	27	3 (11.1)	N.A. (6.90, N.A.)	1.301 (0.249, 6.784) 0.9092	
DE NOVO METASTATIC	107	21 (19.6)	N.A. (18.69, N.A.)	78	12 (15.4)	15.01 (10.25, N.A.)	0.759 (0.358, 1.606) 0.6268	
UNRESECTABLE ADVANCED	18	3 (16.7)	N.A. (5.62, N.A.)	24	5 (20.8)	N.A. (8.67, N.A.)	0.555 (0.130, 2.365) 0.4905	
SMOKING STATUS								0.1662
CURRENT/FORMER	134	25 (18.7)	N.A. (18.69, N.A.)	109	15 (13.8)	N.A. (11.14, N.A.)	0.900 (0.463, 1.751) 0.9862	
NEVER/UNKNOWN	22	3 (13.6)	N.A. (5.52, N.A.)	32	8 (25.0)	15.01 (7.98, N.A.)	0.268 (0.060, 1.195) 0.1539	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 35 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.7432
CURRENT/FORMER	124	22 (17.7)	N.A. (19.02, N.A.)	116	19 (16.4)	18.76 (10.25, N.A.)	0.654 (0.341, 1.255) 0.4154	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (12.68, N.A.)	25	4 (16.0)	15.01 (N.A., N.A.)	0.982 (0.271, 3.553) 0.9668	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4242
<= 1	79	15 (19.0)	N.A. (18.69, N.A.)	68	9 (13.2)	N.A. (11.14, N.A.)	0.950 (0.402, 2.242) 0.8713	
>= 2	77	13 (16.9)	N.A. (19.02, N.A.)	73	14 (19.2)	15.01 (10.25, N.A.)	0.557 (0.249, 1.242) 0.2226	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 36 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.7929
< 1 YEAR	128	23 (18.0)	N.A. (19.02, N.A.)	112	18 (16.1)	15.01 (10.25, N.A.)	0.640 (0.332, 1.232) 0.3218	
1 - < 3 YEARS	23	5 (21.7)	N.A. (4.14, N.A.)	20	4 (20.0)	N.A. (7.98, N.A.)	1.043 (0.278, 3.910) 0.9254	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4619
YES	36	5 (13.9)	N.A.	36	3 (8.3)	N.A.	1.285 (0.304, 5.422) 0.5138	
NO	120	23 (19.2)	N.A. (18.69, N.A.)	105	20 (19.0)	15.01 (10.25, N.A.)	0.613 (0.324, 1.160) 0.2048	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 37 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.7666
YES	24	4 (16.7)	N.A. (4.14, N.A.)	26	5 (19.2)	N.A. (6.90, N.A.)	0.836 (0.222, 3.151) 0.8978	
NO	132	24 (18.2)	N.A. (19.02, N.A.)	115	18 (15.7)	15.01 (11.14, N.A.)	0.718 (0.377, 1.369) 0.4892	
PD-L1 CPS I								0.5806
< 10	51	7 (13.7)	N.A.	51	8 (15.7)	11.14 (11.14, N.A.)	0.443 (0.145, 1.355) 0.2990	
>= 10	92	17 (18.5)	N.A. (18.69, N.A.)	88	15 (17.0)	15.01 (10.25, N.A.)	0.772 (0.376, 1.583) 0.6192	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:10:46

Protocol: CA209648 Page 38 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.6429
< 5	28	4 (14.3)	N.A. (5.42, N.A.)	22	3 (13.6)	N.A. (5.59, N.A.)	1.056 (0.232, 4.804) 0.9903	
>= 5	115	20 (17.4)	N.A. (18.69, N.A.)	117	20 (17.1)	15.01 (11.14, N.A.)	0.616 (0.321, 1.184) 0.2796	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.0234*
< 10%	54	7 (13.0)	N.A.	55	14 (25.5)	15.01 (8.67, N.A.)	0.291 (0.115, 0.740) 0.0154	
>= 10%	102	21 (20.6)	N.A. (18.69, N.A.)	86	9 (10.5)	N.A. (11.14, N.A.)	1.435 (0.631, 3.263) 0.3164	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 39 of 39

SWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: SWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.0931
< 5%	37	5 (13.5)	N.A. (10.38, N.A.)	39	11 (28.2)	18.76 (8.67, N.A.)	0.288 (0.095, 0.880) 0.0473	
>= 5%	119	23 (19.3)	N.A. (18.69, N.A.)	102	12 (11.8)	15.01 (11.14, N.A.)	1.065 (0.512, 2.216) 0.6772	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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3.26 Subgruppenanalysen – FACT-G Subskala EWB (MID = 2, 3, 4)

Protocol: CA209648 Page 1 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	48 (30.8)	18.69 (13.60, N.A.)	141	53 (37.6)	9.00 (7.62, 15.67)	0.532 (0.352, 0.803) 0.0039	
AGE								0.1903
< 65	93	28 (30.1)	25.07 (9.53, N.A.)	74	25 (33.8)	13.60 (8.54, N.A.)	0.634 (0.362, 1.108) 0.1520	
>= 65 AND < 75	55	18 (32.7)	18.50 (8.31, N.A.)	55	22 (40.0)	8.15 (5.03, N.A.)	0.535 (0.273, 1.048) 0.0602	
>= 75	8	2 (25.0)	N.A. (5.36, N.A.)	12	6 (50.0)	5.55 (0.59, N.A.)	0.099 (0.011, 0.860) 0.0183	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 2 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7307
MALE	129	41 (31.8)	18.50 (13.60, 26.58)	121	45 (37.2)	8.90 (7.62, 15.67)	0.515 (0.328, 0.809) 0.0070	
FEMALE	27	7 (25.9)	N.A. (5.36, N.A.)	20	8 (40.0)	10.25 (2.86, N.A.)	0.577 (0.208, 1.600) 0.2847	
RACE								0.2984
ASIAN	117	40 (34.2)	16.99 (9.53, 26.58)	103	40 (38.8)	8.90 (7.62, N.A.)	0.594 (0.374, 0.944) 0.0334	
NON-ASIAN	39	8 (20.5)	N.A. (18.50, N.A.)	38	13 (34.2)	13.60 (4.24, N.A.)	0.344 (0.129, 0.918) 0.0362	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 3 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4714
J/K/T	91	31 (34.1)	16.99 (13.50, N.A.)	84	33 (39.3)	8.90 (7.62, N.A.)	0.553 (0.326, 0.936) 0.0315	
REST OF ASIA	25	9 (36.0)	7.00 (4.44, N.A.)	19	7 (36.8)	9.00 (2.56, N.A.)	0.824 (0.305, 2.227) 0.6926	
REST OF WORLD	40	8 (20.0)	N.A. (18.50, N.A.)	38	13 (34.2)	13.60 (4.24, N.A.)	0.328 (0.123, 0.877) 0.0294	
REGION								0.2498
ASIA	116	40 (34.5)	14.72 (9.53, 26.58)	103	40 (38.8)	8.90 (7.62, N.A.)	0.604 (0.380, 0.959) 0.0393	
NON-ASIA	40	8 (20.0)	N.A. (18.50, N.A.)	38	13 (34.2)	13.60 (4.24, N.A.)	0.328 (0.123, 0.877) 0.0294	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 4 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7962
0	71	25 (35.2)	14.72 (9.53, N.A.)	68	31 (45.6)	8.90 (5.59, N.A.)	0.504 (0.292, 0.873) 0.0141	
1	85	23 (27.1)	18.69 (14.32, N.A.)	71	22 (31.0)	13.60 (5.55, N.A.)	0.608 (0.322, 1.147) 0.1348	
WEIGHT								0.7931
< 60 KG	95	29 (30.5)	20.83 (8.31, N.A.)	74	27 (36.5)	9.00 (5.68, N.A.)	0.586 (0.337, 1.020) 0.0753	
>= 60 KG	61	19 (31.1)	18.69 (13.60, N.A.)	67	26 (38.8)	8.54 (5.55, N.A.)	0.480 (0.256, 0.900) 0.0185	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.3577
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	3 (60.0)	8.72 (8.15, N.A.)	0.843 (0.132, 5.385) 0.7928	
STAGE II	5	3 (60.0)	5.65 (2.76, N.A.)	5	2 (40.0)	N.A. (0.53, N.A.)	0.554 (0.042, 7.374) 0.7660	
STAGE III	31	12 (38.7)	13.50 (6.34, N.A.)	45	12 (26.7)	15.67 (8.90, N.A.)	0.814 (0.345, 1.923) 0.7872	
STAGE IV	114	30 (26.3)	25.07 (14.72, N.A.)	86	36 (41.9)	9.00 (4.70, N.A.)	0.410 (0.245, 0.686) 0.0006	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.6363
GX	11	2 (18.2)	N.A. (1.48, N.A.)	14	4 (28.6)	8.54 (3.75, N.A.)	0.680 (0.094, 4.927) 0.8121	
G1	8	2 (25.0)	N.A. (3.84, N.A.)	7	4 (57.1)	4.70 (2.96, N.A.)	0.250 (0.027, 2.280) 0.2047	
G2	58	20 (34.5)	18.69 (8.48, N.A.)	47	13 (27.7)	18.76 (8.15, N.A.)	0.748 (0.361, 1.549) 0.4750	
G3	27	7 (25.9)	20.83 (6.97, N.A.)	36	12 (33.3)	15.67 (4.24, N.A.)	0.363 (0.117, 1.127) 0.0742	
NOT OTHERWISE SPECIFIED	50	16 (32.0)	13.50 (6.34, N.A.)	37	20 (54.1)	5.59 (3.75, 9.00)	0.429 (0.218, 0.842) 0.0091	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 7 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7262
UPPER THORACIC	35	11 (31.4)	14.32 (13.50, N.A.)	24	10 (41.7)	8.15 (2.96, N.A.)	0.474 (0.198, 1.134) 0.0658	
MIDDLE THORACIC	50	12 (24.0)	25.07 (8.31, N.A.)	50	17 (34.0)	10.25 (5.68, N.A.)	0.495 (0.222, 1.105) 0.0833	
LOWER THORACIC	59	18 (30.5)	20.83 (9.53, N.A.)	59	23 (39.0)	8.90 (4.24, N.A.)	0.506 (0.263, 0.975) 0.0411	
GASTROESOPHAGEAL JUNCTION	11	6 (54.5)	3.78 (1.15, N.A.)	8	3 (37.5)	N.A. (0.53, N.A.)	1.406 (0.331, 5.985) 0.6148	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 8 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.1088
RECURRENT - LOCO-REGIONAL	7	4 (57.1)	8.48 (2.76, N.A.)	12	3 (25.0)	N.A. (5.03, N.A.)	2.776 (0.616, 12.516) 0.1688	
RECURRENT - DISTANT	24	10 (41.7)	9.53 (5.65, 26.58)	27	9 (33.3)	8.90 (4.24, N.A.)	0.885 (0.329, 2.376) 0.6589	
DE NOVO METASTATIC	107	26 (24.3)	N.A. (14.32, N.A.)	78	33 (42.3)	9.00 (4.70, N.A.)	0.384 (0.223, 0.661) 0.0005	
UNRESECTABLE ADVANCED	18	8 (44.4)	18.50 (5.52, N.A.)	24	8 (33.3)	15.67 (3.75, N.A.)	0.507 (0.160, 1.603) 0.3595	
SMOKING STATUS								0.7415
CURRENT/FORMER	134	41 (30.6)	18.69 (13.60, N.A.)	109	39 (35.8)	8.90 (7.62, 15.67)	0.525 (0.328, 0.840) 0.0102	
NEVER/UNKNOWN	22	7 (31.8)	N.A. (5.36, N.A.)	32	14 (43.8)	9.00 (3.29, N.A.)	0.574 (0.227, 1.452) 0.2850	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 9 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.4740
CURRENT/FORMER	124	39 (31.5)	18.69 (13.60, N.A.)	116	42 (36.2)	10.25 (7.62, N.A.)	0.558 (0.351, 0.887) 0.0168	
NEVER/UNKNOWN	32	9 (28.1)	N.A. (6.97, N.A.)	25	11 (44.0)	9.00 (3.75, N.A.)	0.433 (0.175, 1.075) 0.1055	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.8730
<= 1	79	23 (29.1)	18.69 (13.50, N.A.)	68	26 (38.2)	8.90 (6.18, 15.67)	0.490 (0.270, 0.890) 0.0180	
>= 2	77	25 (32.5)	20.83 (13.60, N.A.)	73	27 (37.0)	9.00 (5.59, N.A.)	0.575 (0.323, 1.023) 0.1081	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 10 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.1638
< 1 YEAR	128	34 (26.6)	20.83 (14.72, N.A.)	112	43 (38.4)	9.00 (5.68, 15.67)	0.406 (0.250, 0.658) 0.0003	
1 - < 3 YEARS	23	11 (47.8)	8.31 (3.78, 26.58)	20	8 (40.0)	8.90 (0.95, N.A.)	1.000 (0.390, 2.561) 0.9500	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.1541
YES	36	15 (41.7)	9.53 (5.65, N.A.)	36	12 (33.3)	8.90 (8.15, N.A.)	0.943 (0.434, 2.053) 0.9031	
NO	120	33 (27.5)	20.83 (14.72, N.A.)	105	41 (39.0)	10.25 (5.59, 15.67)	0.440 (0.269, 0.719) 0.0014	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 11 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2068
YES	24	10 (41.7)	13.50 (3.84, N.A.)	26	9 (34.6)	8.90 (2.83, N.A.)	0.970 (0.379, 2.483) 0.9129	
NO	132	38 (28.8)	20.83 (14.32, N.A.)	115	44 (38.3)	9.00 (6.18, 15.67)	0.461 (0.291, 0.732) 0.0017	
PD-L1 CPS I								0.8858
< 10	51	17 (33.3)	18.50 (8.31, N.A.)	51	16 (31.4)	18.76 (4.70, N.A.)	0.579 (0.282, 1.189) 0.2727	
>= 10	92	28 (30.4)	16.99 (13.60, N.A.)	88	37 (42.0)	8.90 (6.18, 15.67)	0.529 (0.316, 0.887) 0.0146	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 12 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.6410
< 5	28	7 (25.0)	25.07 (5.42, N.A.)	22	8 (36.4)	N.A. (2.86, N.A.)	0.500 (0.171, 1.458) 0.3583	
>= 5	115	38 (33.0)	16.99 (13.50, N.A.)	117	45 (38.5)	9.00 (7.62, 15.67)	0.556 (0.354, 0.873) 0.0124	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9787
< 10%	54	16 (29.6)	18.50 (13.50, N.A.)	55	18 (32.7)	13.60 (5.26, N.A.)	0.482 (0.237, 0.979) 0.1025	
>= 10%	102	32 (31.4)	18.69 (8.48, N.A.)	86	35 (40.7)	8.90 (5.68, N.A.)	0.568 (0.342, 0.943) 0.0266	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 13 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.4918
< 5%	37	12 (32.4)	25.07 (9.53, N.A.)	39	13 (33.3)	13.60 (5.03, N.A.)	0.609 (0.270, 1.374) 0.3144	
>= 5%	119	36 (30.3)	18.69 (13.50, N.A.)	102	40 (39.2)	8.90 (5.68, N.A.)	0.504 (0.312, 0.816) 0.0060	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 14 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	35 (22.4)	26.58 (20.83, N.A.)	141	37 (26.2)	13.60 (8.90, N.A.)	0.591 (0.364, 0.962) 0.0421	
AGE								0.4363
< 65	93	20 (21.5)	26.58 (14.72, N.A.)	74	18 (24.3)	13.60 (8.90, N.A.)	0.647 (0.334, 1.256) 0.2561	
>= 65 AND < 75	55	13 (23.6)	N.A. (14.32, N.A.)	55	15 (27.3)	N.A. (6.54, N.A.)	0.670 (0.307, 1.466) 0.2859	
>= 75	8	2 (25.0)	N.A. (5.36, N.A.)	12	4 (33.3)	5.55 (0.59, N.A.)	0.168 (0.018, 1.617) 0.1019	

Oct 2021 DBL. HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E = Not meaningful estimate; N.E. = Not estimable.
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(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 15 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7884
MALE	129	29 (22.5)	26.58 (18.69, N.A.)	121	32 (26.4)	13.60 (8.54, N.A.)	0.547 (0.320, 0.934) 0.0391	
FEMALE	27	6 (22.2)	N.A. (5.55, N.A.)	20	5 (25.0)	12.88 (4.47, N.A.)	0.822 (0.249, 2.708) 0.7468	
RACE								0.4575
ASIAN	117	29 (24.8)	26.58 (14.72, N.A.)	103	28 (27.2)	12.88 (8.90, N.A.)	0.653 (0.378, 1.129) 0.1474	
NON-ASIAN	39	6 (15.4)	N.A. (18.69, N.A.)	38	9 (23.7)	13.60 (6.54, N.A.)	0.398 (0.130, 1.218) 0.1087	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 16 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4220
J/K/T	91	20 (22.0)	26.58 (20.83, N.A.)	84	23 (27.4)	12.88 (8.54, N.A.)	0.548 (0.288, 1.045) 0.0753	
REST OF ASIA	25	9 (36.0)	12.68 (4.44, N.A.)	19	5 (26.3)	N.A. (2.56, N.A.)	1.035 (0.337, 3.177) 0.9567	
REST OF WORLD	40	6 (15.0)	N.A. (18.69, N.A.)	38	9 (23.7)	13.60 (6.54, N.A.)	0.380 (0.124, 1.164) 0.0931	
REGION								0.3970
ASIA	116	29 (25.0)	26.58 (14.72, N.A.)	103	28 (27.2)	12.88 (8.90, N.A.)	0.664 (0.385, 1.147) 0.1637	
NON-ASIA	40	6 (15.0)	N.A. (18.69, N.A.)	38	9 (23.7)	13.60 (6.54, N.A.)	0.380 (0.124, 1.164) 0.0931	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 17 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.5223
0	71	16 (22.5)	26.58 (14.72, N.A.)	68	21 (30.9)	12.88 (8.15, N.A.)	0.487 (0.246, 0.964) 0.0359	
1	85	19 (22.4)	25.07 (14.32, N.A.)	71	16 (22.5)	13.60 (8.90, N.A.)	0.753 (0.370, 1.531) 0.4302	
WEIGHT								0.8570
< 60 KG	95	20 (21.1)	26.58 (14.32, N.A.)	74	19 (25.7)	12.88 (8.90, N.A.)	0.569 (0.293, 1.105) 0.1382	
>= 60 KG	61	15 (24.6)	N.A. (14.72, N.A.)	67	18 (26.9)	13.60 (6.54, N.A.)	0.613 (0.297, 1.265) 0.1677	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 18 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.7892
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	3 (60.0)	8.72 (8.15, N.A.)	0.843 (0.132, 5.385) 0.7928	
STAGE II	5	2 (40.0)	N.A. (2.76, N.A.)	5	1 (20.0)	N.A. (0.53, N.A.)	1.897 (0.102, 35.299) 0.9802	
STAGE III	31	6 (19.4)	N.A. (9.92, N.A.)	45	7 (15.6)	N.A.	0.822 (0.259, 2.607) 0.8214	
STAGE IV	114	24 (21.1)	N.A. (18.69, N.A.)	86	26 (30.2)	12.88 (6.54, N.A.)	0.487 (0.270, 0.879) 0.0165	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 19 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2748
GX	11	1 (9.1)	N.A. (1.97, N.A.)	14	3 (21.4)	N.A. (5.68, N.A.)	0.634 (0.046, 8.766) 0.5956	
G1	8	2 (25.0)	N.A. (3.84, N.A.)	7	4 (57.1)	5.62 (4.17, N.A.)	0.280 (0.031, 2.537) 0.2242	
G2	58	16 (27.6)	25.07 (14.32, N.A.)	47	8 (17.0)	N.A. (8.90, N.A.)	0.977 (0.404, 2.366) 0.9907	
G3	27	6 (22.2)	N.A. (12.68, N.A.)	36	6 (16.7)	N.A.	0.755 (0.203, 2.803) 0.6769	
NOT OTHERWISE SPECIFIED	50	10 (20.0)	N.A. (8.31, N.A.)	37	16 (43.2)	6.18 (5.26, N.A.)	0.368 (0.165, 0.819) 0.0090	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 20 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9245
UPPER THORACIC	35	6 (17.1)	N.A. (14.32, N.A.)	24	6 (25.0)	9.00 (5.59, N.A.)	0.474 (0.150, 1.496) 0.1885	
MIDDLE THORACIC	50	9 (18.0)	N.A. (18.69, N.A.)	50	13 (26.0)	12.88 (8.54, N.A.)	0.495 (0.195, 1.253) 0.1341	
LOWER THORACIC	59	16 (27.1)	26.58 (12.68, N.A.)	59	15 (25.4)	N.A. (6.18, N.A.)	0.727 (0.343, 1.540) 0.4106	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	N.A. (1.22, N.A.)	8	3 (37.5)	N.A. (0.53, N.A.)	0.744 (0.115, 4.809) 0.5738	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 21 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5130
RECURRENT - LOCO-REGIONAL	7	2 (28.6)	N.A. (2.76, N.A.)	12	2 (16.7)	N.A. (8.15, N.A.)	1.628 (0.226, 11.707) 0.6246	
RECURRENT - DISTANT	24	6 (25.0)	26.58 (7.00, N.A.)	27	5 (18.5)	N.A. (8.90, N.A.)	1.001 (0.283, 3.546) 0.9572	
DE NOVO METASTATIC	107	20 (18.7)	N.A. (18.69, N.A.)	78	23 (29.5)	12.88 (6.54, N.A.)	0.466 (0.248, 0.875) 0.0177	
UNRESECTABLE ADVANCED	18	7 (38.9)	25.07 (5.52, N.A.)	24	7 (29.2)	N.A. (4.17, N.A.)	0.654 (0.207, 2.069) 0.6286	
SMOKING STATUS								0.8675
CURRENT/FORMER	134	29 (21.6)	26.58 (18.69, N.A.)	109	26 (23.9)	13.60 (8.90, N.A.)	0.582 (0.330, 1.026) 0.0784	
NEVER/UNKNOWN	22	6 (27.3)	N.A. (5.36, N.A.)	32	11 (34.4)	12.88 (5.62, N.A.)	0.745 (0.274, 2.027) 0.5773	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 22 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.8275
CURRENT/FORMER	124	27 (21.8)	26.58 (20.83, N.A.)	116	29 (25.0)	12.88 (8.90, N.A.)	0.614 (0.353, 1.067) 0.0986	
NEVER/UNKNOWN	32	8 (25.0)	14.32 (7.00, N.A.)	25	8 (32.0)	9.00 (5.26, N.A.)	0.544 (0.198, 1.494) 0.2553	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.7550
<= 1	79	17 (21.5)	26.58 (14.72, N.A.)	68	19 (27.9)	13.60 (8.54, N.A.)	0.512 (0.256, 1.023) 0.0544	
>= 2	77	18 (23.4)	N.A. (20.83, N.A.)	73	18 (24.7)	12.88 (8.15, N.A.)	0.678 (0.340, 1.351) 0.3687	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 23 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2339
< 1 YEAR	128	26 (20.3)	N.A. (20.83, N.A.)	112	31 (27.7)	12.88 (9.00, N.A.)	0.485 (0.279, 0.844) 0.0133	
1 - < 3 YEARS	23	7 (30.4)	9.92 (3.84, N.A.)	20	4 (20.0)	N.A. (8.90, N.A.)	1.276 (0.358, 4.544) 0.6988	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.3513
YES	36	10 (27.8)	26.58 (8.31, N.A.)	36	8 (22.2)	N.A. (8.54, N.A.)	0.891 (0.339, 2.340) 0.8178	
NO	120	25 (20.8)	N.A. (20.83, N.A.)	105	29 (27.6)	12.88 (9.00, N.A.)	0.538 (0.306, 0.946) 0.0399	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 24 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2032
YES	24	6 (25.0)	26.58 (3.84, N.A.)	26	4 (15.4)	N.A. (8.15, N.A.)	1.364 (0.365, 5.101) 0.6381	
NO	132	29 (22.0)	N.A. (18.69, N.A.)	115	33 (28.7)	12.88 (8.54, N.A.)	0.509 (0.300, 0.862) 0.0162	
PD-L1 CPS I								0.7771
< 10	51	10 (19.6)	25.07 (25.07, N.A.)	51	9 (17.6)	N.A. (6.54, N.A.)	0.747 (0.291, 1.916) 0.6942	
>= 10	92	22 (23.9)	26.58 (14.32, N.A.)	88	28 (31.8)	12.88 (8.54, N.A.)	0.552 (0.306, 0.995) 0.0432	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 25 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.3096
< 5	28	6 (21.4)	25.07 (5.42, N.A.)	22	3 (13.6)	N.A.	1.225 (0.290, 5.168) 0.6041	
>= 5	115	26 (22.6)	N.A. (14.72, N.A.)	117	34 (29.1)	12.88 (8.54, N.A.)	0.538 (0.316, 0.915) 0.0235	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9574
< 10%	54	10 (18.5)	N.A. (25.07, N.A.)	55	11 (20.0)	13.60 (6.54, N.A.)	0.556 (0.226, 1.368) 0.3446	
>= 10%	102	25 (24.5)	26.58 (14.32, N.A.)	86	26 (30.2)	12.88 (8.54, N.A.)	0.585 (0.325, 1.054) 0.0680	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 26 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2188
< 5%	37	9 (24.3)	N.A. (25.07, N.A.)	39	7 (17.9)	13.60 (9.00, N.A.)	0.953 (0.344, 2.642) 0.9499	
>= 5%	119	26 (21.8)	26.58 (18.69, N.A.)	102	30 (29.4)	12.88 (8.15, N.A.)	0.501 (0.286, 0.877) 0.0168	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 27 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	27 (17.3)	27.83 (20.83, N.A.)	141	27 (19.1)	13.60 (12.88, N.A.)	0.587 (0.334, 1.032) 0.0778	
AGE								0.6508
< 65	93	15 (16.1)	27.83 (N.A., N.A.)	74	13 (17.6)	13.60 (12.88, N.A.)	0.689 (0.320, 1.480) 0.4117	
>= 65 AND < 75	55	10 (18.2)	N.A. (16.39, N.A.)	55	11 (20.0)	N.A. (9.00, N.A.)	0.584 (0.232, 1.469) 0.2384	
>= 75	8	2 (25.0)	N.A. (5.36, N.A.)	12	3 (25.0)	N.A. (0.59, N.A.)	0.275 (0.025, 3.003) 0.2572	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 28 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9699
MALE	129	24 (18.6)	27.83 (20.83, N.A.)	121	24 (19.8)	13.60 (9.13, N.A.)	0.579 (0.317, 1.057) 0.1018	
FEMALE	27	3 (11.1)	N.A.	20	3 (15.0)	12.88 (9.00, N.A.)	0.692 (0.138, 3.474) 0.6449	
RACE								0.7241
ASIAN	117	21 (17.9)	27.83 (20.83, N.A.)	103	22 (21.4)	12.88 (9.13, N.A.)	0.579 (0.308, 1.090) 0.1064	
NON-ASIAN	39	6 (15.4)	N.A. (18.69, N.A.)	38	5 (13.2)	N.A. (13.60, N.A.)	0.733 (0.207, 2.600) 0.6498	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 29 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.7027
J/K/T	91	15 (16.5)	27.83 (20.83, N.A.)	84	18 (21.4)	12.88 (9.13, N.A.)	0.513 (0.246, 1.069) 0.0877	
REST OF ASIA	25	6 (24.0)	12.68 (5.52, N.A.)	19	4 (21.1)	N.A. (2.56, N.A.)	0.801 (0.214, 2.998) 0.7496	
REST OF WORLD	40	6 (15.0)	N.A. (18.69, N.A.)	38	5 (13.2)	N.A. (13.60, N.A.)	0.699 (0.197, 2.485) 0.6060	
REGION								0.8045
ASIA	116	21 (18.1)	27.83 (20.83, N.A.)	103	22 (21.4)	12.88 (9.13, N.A.)	0.590 (0.314, 1.110) 0.1187	
NON-ASIA	40	6 (15.0)	N.A. (18.69, N.A.)	38	5 (13.2)	N.A. (13.60, N.A.)	0.699 (0.197, 2.485) 0.6060	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 30 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.3614
0	71	13 (18.3)	N.A. (20.83, N.A.)	68	18 (26.5)	N.A. (9.00, N.A.)	0.485 (0.232, 1.013) 0.0541	
1	85	14 (16.5)	27.83 (18.69, N.A.)	71	9 (12.7)	13.60 (9.13, N.A.)	0.837 (0.333, 2.107) 0.6598	
WEIGHT								0.7203
< 60 KG	95	16 (16.8)	N.A. (20.83, N.A.)	74	16 (21.6)	12.88 (9.00, N.A.)	0.522 (0.250, 1.090) 0.1348	
>= 60 KG	61	11 (18.0)	27.83 (18.69, N.A.)	67	11 (16.4)	13.60 (9.13, N.A.)	0.611 (0.249, 1.498) 0.2694	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 31 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9639
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	3 (60.0)	8.72 (8.15, N.A.)	0.843 (0.132, 5.385) 0.7928	
STAGE II	5	1 (20.0)	N.A. (3.84, N.A.)	5	0	N.E.	N.E. 0.5637	
STAGE III	31	4 (12.9)	N.A. (12.68, N.A.)	45	5 (11.1)	N.A.	0.822 (0.212, 3.189) 0.8984	
STAGE IV	114	19 (16.7)	27.83 (20.83, N.A.)	86	19 (22.1)	12.88 (9.13, N.A.)	0.471 (0.238, 0.935) 0.0330	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 32 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2153
GX	11	1 (9.1)	N.A. (1.97, N.A.)	14	3 (21.4)	N.A. (5.68, N.A.)	0.634 (0.046, 8.766) 0.5956	
G1	8	2 (25.0)	N.A. (3.84, N.A.)	7	3 (42.9)	5.62 (4.17, N.A.)	0.365 (0.037, 3.566) 0.3673	
G2	58	13 (22.4)	27.83 (16.39, N.A.)	47	5 (10.6)	N.A. (8.90, N.A.)	1.359 (0.465, 3.978) 0.6101	
G3	27	5 (18.5)	N.A. (12.68, N.A.)	36	4 (11.1)	N.A.	1.120 (0.254, 4.937) 0.9355	
NOT OTHERWISE SPECIFIED	50	6 (12.0)	N.A. (10.91, N.A.)	37	12 (32.4)	9.13 (5.78, N.A.)	0.225 (0.080, 0.631) 0.0044	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 33 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8645
UPPER THORACIC	35	6 (17.1)	N.A. (16.39, N.A.)	24	5 (20.8)	9.00 (8.15, N.A.)	0.569 (0.170, 1.904) 0.3570	
MIDDLE THORACIC	50	7 (14.0)	27.83 (18.69, N.A.)	50	11 (22.0)	13.60 (8.90, N.A.)	0.407 (0.139, 1.191) 0.0928	
LOWER THORACIC	59	11 (18.6)	N.A. (12.68, N.A.)	59	9 (15.3)	N.A.	0.823 (0.326, 2.079) 0.6858	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A. (1.22, N.A.)	8	2 (25.0)	N.A. (0.53, N.A.)	0.548 (0.045, 6.598) 0.4953	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 34 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.7226
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (12.68, N.A.)	12	2 (16.7)	N.A. (8.15, N.A.)	0.388 (0.025, 6.136) 0.5679	
RECURRENT - DISTANT	24	4 (16.7)	N.A. (7.00, N.A.)	27	4 (14.8)	N.A. (8.90, N.A.)	0.999 (0.245, 4.066) 0.9805	
DE NOVO METASTATIC	107	16 (15.0)	N.A. (18.69, N.A.)	78	17 (21.8)	12.88 (9.00, N.A.)	0.431 (0.208, 0.893) 0.0253	
UNRESECTABLE ADVANCED	18	6 (33.3)	27.83 (5.52, N.A.)	24	4 (16.7)	N.A. (4.17, N.A.)	1.153 (0.302, 4.403) 0.7417	
SMOKING STATUS								0.4003
CURRENT/FORMER	134	25 (18.7)	27.83 (20.83, N.A.)	109	20 (18.3)	13.60 (9.13, N.A.)	0.629 (0.336, 1.179) 0.1842	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	32	7 (21.9)	12.88 (9.00, N.A.)	0.366 (0.074, 1.809) 0.2254	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 35 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.6150
CURRENT/FORMER	124	21 (16.9)	27.83 (20.83, N.A.)	116	20 (17.2)	N.A. (12.88, N.A.)	0.658 (0.345, 1.254) 0.2383	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (12.68, N.A.)	25	7 (28.0)	13.60 (5.26, N.A.)	0.416 (0.129, 1.342) 0.1300	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.5854
<= 1	79	14 (17.7)	N.A. (18.69, N.A.)	68	16 (23.5)	13.60 (9.13, N.A.)	0.529 (0.250, 1.117) 0.0910	
>= 2	77	13 (16.9)	27.83 (20.83, N.A.)	73	11 (15.1)	12.88 (9.00, N.A.)	0.652 (0.272, 1.561) 0.4455	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 36 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.4854
< 1 YEAR	128	21 (16.4)	27.83 (20.83, N.A.)	112	22 (19.6)	13.60 (9.13, N.A.)	0.495 (0.260, 0.943) 0.0454	
1 - < 3 YEARS	23	4 (17.4)	N.A. (8.31, N.A.)	20	3 (15.0)	N.A. (8.90, N.A.)	1.024 (0.220, 4.768) 0.9734	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.5007
YES	36	7 (19.4)	N.A. (12.68, N.A.)	36	6 (16.7)	N.A. (8.54, N.A.)	0.824 (0.265, 2.562) 0.7332	
NO	120	20 (16.7)	27.83 (20.83, N.A.)	105	21 (20.0)	13.60 (12.88, N.A.)	0.542 (0.282, 1.041) 0.0912	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 37 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9039
YES	24	3 (12.5)	N.A. (8.15, N.A.)	26	4 (15.4)	N.A. (8.15, N.A.)	0.828 (0.184, 3.714) 0.8242	
NO	132	24 (18.2)	27.83 (20.83, N.A.)	115	23 (20.0)	13.60 (9.13, N.A.)	0.545 (0.296, 1.005) 0.0685	
PD-L1 CPS I								0.9847
< 10	51	9 (17.6)	27.83 (N.A., N.A.)	51	8 (15.7)	N.A. (N.A., N.A.)	0.790 (0.289, 2.160) 0.7579	
>= 10	92	16 (17.4)	N.A. (16.39, N.A.)	88	19 (21.6)	13.60 (9.13, N.A.)	0.545 (0.269, 1.101) 0.0868	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 38 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.6798
< 5	28	5 (17.9)	27.83 (5.42, N.A.)	22	3 (13.6)	N.A.	1.001 (0.222, 4.518) 0.8220	
>= 5	115	20 (17.4)	N.A. (18.69, N.A.)	117	24 (20.5)	13.60 (9.13, N.A.)	0.560 (0.303, 1.036) 0.0709	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.7466
< 10%	54	9 (16.7)	27.83 (N.A., N.A.)	55	10 (18.2)	13.60 (9.00, N.A.)	0.542 (0.208, 1.407) 0.3019	
>= 10%	102	18 (17.6)	N.A. (18.69, N.A.)	86	17 (19.8)	12.88 (12.88, N.A.)	0.591 (0.288, 1.214) 0.1473	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:28:57

Protocol: CA209648 Page 39 of 39

EWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: EWB (MID=4)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.3049
< 5%	37	8 (21.6)	27.83 (N.A., N.A.)	39	6 (15.4)	13.60 (9.00, N.A.)	0.957 (0.319, 2.869) 0.9745	
>= 5%	119	19 (16.0)	N.A. (18.69, N.A.)	102	21 (20.6)	12.88 (9.13, N.A.)	0.480 (0.245, 0.940) 0.0367	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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3.27 Subgruppenanalysen – FACT-G Subskala FWB (MID = 2, 3, 5)

Protocol: CA209648 Page 1 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	84 (53.8)	6.11 (4.63, 11.96)	140	63 (45.0)	8.54 (5.68, 11.14)	0.939 (0.671, 1.314) 0.9414	
AGE								0.8602
< 65	93	50 (53.8)	8.08 (4.63, 15.31)	74	35 (47.3)	8.54 (5.26, 15.01)	0.896 (0.574, 1.397) 0.8940	
>= 65 AND < 75	55	27 (49.1)	6.11 (2.99, N.A.)	54	23 (42.6)	7.43 (5.03, 10.51)	1.007 (0.573, 1.771) 0.9244	
>= 75	8	7 (87.5)	3.01 (0.53, N.A.)	12	5 (41.7)	6.01 (0.59, N.A.)	1.456 (0.361, 5.882) 0.3711	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:32:59

Protocol: CA209648 Page 2 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6145
MALE	129	71 (55.0)	6.11 (4.30, 12.48)	120	58 (48.3)	7.43 (5.59, 9.76)	0.918 (0.643, 1.311) 0.9024	
FEMALE	27	13 (48.1)	11.96 (2.89, N.A.)	20	5 (25.0)	15.01 (4.21, N.A.)	1.410 (0.480, 4.142) 0.5022	
RACE								0.3984
ASIAN	117	70 (59.8)	5.65 (4.01, 11.43)	103	50 (48.5)	7.43 (5.03, 10.51)	1.022 (0.705, 1.482) 0.7351	
NON-ASIAN	39	14 (35.9)	18.40 (5.13, N.A.)	37	13 (35.1)	13.60 (5.68, N.A.)	0.634 (0.280, 1.434) 0.5516	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 3 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.7595
J/K/T	91	53 (58.2)	6.01 (2.92, 12.48)	84	38 (45.2)	8.54 (5.59, 15.67)	1.006 (0.654, 1.548) 0.6490	
REST OF ASIA	25	16 (64.0)	4.63 (1.77, 11.43)	19	12 (63.2)	4.21 (0.95, N.A.)	0.806 (0.361, 1.799) 0.6269	
REST OF WORLD	40	15 (37.5)	18.40 (5.13, N.A.)	37	13 (35.1)	13.60 (5.68, N.A.)	0.667 (0.300, 1.484) 0.6430	
REGION								0.4561
ASIA	116	69 (59.5)	5.75 (3.48, 11.43)	103	50 (48.5)	7.43 (5.03, 10.51)	1.016 (0.700, 1.475) 0.7598	
NON-ASIA	40	15 (37.5)	18.40 (5.13, N.A.)	37	13 (35.1)	13.60 (5.68, N.A.)	0.667 (0.300, 1.484) 0.6430	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 4 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.4673
0	71	46 (64.8)	5.75 (3.48, 11.96)	68	35 (51.5)	5.91 (4.17, 11.14)	0.829 (0.523, 1.313) 0.9386	
1	85	38 (44.7)	8.74 (4.17, 27.76)	70	27 (38.6)	9.13 (5.85, 13.60)	1.088 (0.653, 1.813) 0.8229	
WEIGHT								0.1642
< 60 KG	95	53 (55.8)	5.65 (2.92, 8.74)	74	30 (40.5)	10.51 (5.26, N.A.)	1.196 (0.754, 1.897) 0.2825	
>= 60 KG	61	31 (50.8)	11.86 (5.13, 25.07)	66	33 (50.0)	7.59 (3.84, 9.76)	0.693 (0.417, 1.152) 0.2592	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.6507
STAGE I	5	1 (20.0)	N.A. (2.17, N.A.)	5	2 (40.0)	9.53 (8.54, N.A.)	0.007 (<0.001, 6.581) 0.5203	
STAGE II	5	4 (80.0)	2.76 (0.53, N.A.)	5	2 (40.0)	N.A. (0.53, N.A.)	2.773 (0.360, 21.344) 0.5754	
STAGE III	31	17 (54.8)	11.96 (2.79, N.A.)	44	19 (43.2)	10.51 (4.96, 15.67)	0.715 (0.347, 1.472) 0.8960	
STAGE IV	114	61 (53.5)	6.14 (4.30, 12.48)	86	40 (46.5)	7.43 (5.22, 13.60)	0.963 (0.640, 1.447) 0.9019	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9444
GX	11	7 (63.6)	1.81 (0.53, N.A.)	14	7 (50.0)	8.54 (2.83, N.A.)	1.038 (0.286, 3.774) 0.3862	
G1	8	4 (50.0)	4.63 (0.53, N.A.)	7	2 (28.6)	N.A. (4.17, N.A.)	2.214 (0.399, 12.297) 0.3244	
G2	58	29 (50.0)	11.43 (5.13, 20.83)	46	17 (37.0)	11.14 (4.93, N.A.)	0.884 (0.475, 1.647) 0.9777	
G3	27	15 (55.6)	11.86 (0.99, 27.76)	36	16 (44.4)	9.76 (5.85, N.A.)	0.879 (0.409, 1.885) 0.6649	
NOT OTHERWISE SPECIFIED	50	27 (54.0)	5.65 (2.76, N.A.)	37	21 (56.8)	5.59 (4.21, 9.13)	0.851 (0.477, 1.518) 0.6696	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 7 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.6237
UPPER THORACIC	35	22 (62.9)	6.14 (2.79, 12.48)	24	11 (45.8)	5.59 (4.21, N.A.)	0.952 (0.452, 2.005) 0.9588	
MIDDLE THORACIC	50	29 (58.0)	5.65 (1.74, 20.83)	50	22 (44.0)	11.14 (5.26, 15.01)	1.227 (0.687, 2.190) 0.3378	
LOWER THORACIC	59	28 (47.5)	11.86 (4.30, N.A.)	59	28 (47.5)	7.59 (3.75, 9.76)	0.719 (0.417, 1.239) 0.2840	
GASTROESOPHAGEAL JUNCTION	11	5 (45.5)	5.62 (0.66, N.A.)	7	2 (28.6)	N.A. (0.53, N.A.)	1.250 (0.228, 6.855) 0.5249	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 8 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.7113
RECURRENT - LOCO-REGIONAL	7	4 (57.1)	18.40 (0.53, N.A.)	12	6 (50.0)	8.54 (1.45, N.A.)	0.775 (0.153, 3.933) 0.8615	
RECURRENT - DISTANT	24	12 (50.0)	5.65 (2.10, N.A.)	27	9 (33.3)	10.51 (4.93, N.A.)	1.586 (0.644, 3.902) 0.4546	
DE NOVO METASTATIC	107	56 (52.3)	6.14 (4.30, 15.31)	78	36 (46.2)	7.43 (5.22, 13.60)	0.942 (0.614, 1.444) 0.9075	
UNRESECTABLE ADVANCED	18	12 (66.7)	11.86 (2.17, 25.07)	23	12 (52.2)	6.01 (2.86, N.A.)	0.659 (0.277, 1.566) 0.4857	
SMOKING STATUS								0.7473
CURRENT/FORMER	134	73 (54.5)	6.24 (4.63, 12.48)	109	52 (47.7)	7.43 (5.22, 10.51)	0.877 (0.608, 1.265) 0.6728	
NEVER/UNKNOWN	22	11 (50.0)	5.13 (2.76, N.A.)	31	11 (35.5)	15.01 (5.59, N.A.)	1.132 (0.467, 2.744) 0.4816	

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(1) KME of median time to event.
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 9 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.3600
CURRENT/FORMER	124	70 (56.5)	6.11 (4.30, 11.86)	115	50 (43.5)	9.13 (5.85, 11.14)	0.992 (0.683, 1.441) 0.6367	
NEVER/UNKNOWN	32	14 (43.8)	27.76 (2.73, N.A.)	25	13 (52.0)	5.26 (2.96, N.A.)	0.753 (0.346, 1.639) 0.4927	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.2504
<= 1	79	40 (50.6)	6.60 (5.62, 18.00)	67	32 (47.8)	9.13 (5.62, 13.60)	0.755 (0.467, 1.220) 0.5074	
>= 2	77	44 (57.1)	5.13 (2.76, 15.34)	73	31 (42.5)	7.43 (5.03, 15.01)	1.190 (0.742, 1.907) 0.3876	

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(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 10 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2559
< 1 YEAR	128	67 (52.3)	6.60 (5.13, 15.31)	111	52 (46.8)	6.47 (5.59, 11.14)	0.835 (0.575, 1.212) 0.5247	
1 - < 3 YEARS	23	15 (65.2)	2.79 (0.59, 18.00)	20	8 (40.0)	10.51 (0.95, N.A.)	1.162 (0.462, 2.925) 0.3570	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.3909
YES	36	19 (52.8)	5.62 (2.10, N.A.)	35	14 (40.0)	9.53 (4.96, N.A.)	1.322 (0.654, 2.675) 0.5096	
NO	120	65 (54.2)	6.24 (4.30, 12.48)	105	49 (46.7)	7.43 (5.59, 11.14)	0.876 (0.596, 1.288) 0.7425	

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(1) KME of median time to event.
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 11 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.0611
YES	24	14 (58.3)	4.17 (2.17, 18.00)	26	5 (19.2)	N.A. (5.03, N.A.)	2.447 (0.828, 7.234) 0.0476	
NO	132	70 (53.0)	6.60 (4.63, 15.31)	114	58 (50.9)	7.43 (5.59, 9.76)	0.820 (0.574, 1.173) 0.4021	
PD-L1 CPS I								0.8225
< 10	51	26 (51.0)	5.65 (2.89, 25.07)	51	21 (41.2)	5.68 (4.93, 11.14)	0.998 (0.551, 1.810) 0.8918	
>= 10	92	49 (53.3)	6.24 (4.17, 15.31)	87	41 (47.1)	7.59 (5.85, 15.01)	0.875 (0.570, 1.343) 0.8462	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 12 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.7289
< 5	28	15 (53.6)	4.63 (1.48, N.A.)	22	10 (45.5)	5.03 (1.45, N.A.)	1.064 (0.465, 2.434) 0.8958	
>= 5	115	60 (52.2)	6.60 (5.55, 15.31)	116	52 (44.8)	8.54 (5.68, 13.60)	0.899 (0.614, 1.316) 0.8757	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5481
< 10%	54	27 (50.0)	11.96 (4.30, 25.07)	55	24 (43.6)	9.13 (4.93, 15.01)	0.807 (0.457, 1.428) 0.6644	
>= 10%	102	57 (55.9)	6.01 (3.48, 11.86)	85	39 (45.9)	7.59 (5.62, N.A.)	1.023 (0.673, 1.555) 0.6431	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:32:59

Protocol: CA209648 Page 13 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=2)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.8089
< 5%	37	19 (51.4)	11.96 (2.86, 25.07)	39	16 (41.0)	9.76 (4.93, N.A.)	0.997 (0.500, 1.990) 0.8312	
>= 5%	119	65 (54.6)	6.11 (4.30, 11.86)	101	47 (46.5)	7.59 (5.59, 11.14)	0.913 (0.620, 1.344) 0.9457	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 14 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	76 (48.7)	8.74 (5.65, 18.40)	140	55 (39.3)	9.53 (5.91, 15.01)	0.956 (0.668, 1.368) 0.8140	
AGE								0.8683
< 65	93	45 (48.4)	8.74 (5.65, 18.40)	74	30 (40.5)	11.14 (5.68, 15.67)	0.958 (0.596, 1.541) 0.8502	
>= 65 AND < 75	55	24 (43.6)	15.34 (4.01, N.A.)	54	21 (38.9)	9.13 (5.22, N.A.)	0.947 (0.518, 1.730) 0.8935	
>= 75	8	7 (87.5)	5.68 (0.53, N.A.)	12	4 (33.3)	6.01 (3.84, N.A.)	1.489 (0.298, 7.434) 0.4931	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 15 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9101
MALE	129	65 (50.4)	8.74 (5.65, 18.40)	120	50 (41.7)	9.13 (5.68, 11.14)	0.941 (0.643, 1.377) 0.9273	
FEMALE	27	11 (40.7)	11.96 (2.89, N.A.)	20	5 (25.0)	15.01 (4.21, N.A.)	1.192 (0.404, 3.523) 0.6641	
RACE								0.8815
ASIAN	117	63 (53.8)	8.08 (5.55, 12.48)	103	46 (44.7)	9.13 (5.59, 11.14)	0.985 (0.666, 1.455) 0.8668	
NON-ASIAN	39	13 (33.3)	18.69 (5.36, N.A.)	37	9 (24.3)	15.01 (5.68, N.A.)	0.795 (0.315, 2.003) 0.8613	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 16 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9372
J/K/T	91	48 (52.7)	8.08 (4.30, 19.38)	84	34 (40.5)	9.13 (5.62, N.A.)	1.011 (0.641, 1.595) 0.6054	
REST OF ASIA	25	14 (56.0)	6.24 (1.77, 15.31)	19	12 (63.2)	4.21 (0.95, N.A.)	0.644 (0.281, 1.478) 0.3569	
REST OF WORLD	40	14 (35.0)	18.69 (5.36, N.A.)	37	9 (24.3)	15.01 (5.68, N.A.)	0.812 (0.328, 2.010) 0.8362	
REGION								0.9552
ASIA	116	62 (53.4)	8.08 (4.63, 12.48)	103	46 (44.7)	9.13 (5.59, 11.14)	0.982 (0.663, 1.453) 0.8793	
NON-ASIA	40	14 (35.0)	18.69 (5.36, N.A.)	37	9 (24.3)	15.01 (5.68, N.A.)	0.812 (0.328, 2.010) 0.8362	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 17 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7084
0	71	44 (62.0)	6.11 (4.30, 12.48)	68	31 (45.6)	8.54 (4.73, 15.67)	0.888 (0.547, 1.442) 0.7845	
1	85	32 (37.6)	18.69 (6.24, N.A.)	70	23 (32.9)	9.76 (6.01, N.A.)	1.041 (0.598, 1.815) 0.9530	
WEIGHT								0.0644
< 60 KG	95	48 (50.5)	6.14 (4.30, 15.34)	74	24 (32.4)	11.14 (5.91, N.A.)	1.331 (0.805, 2.202) 0.1302	
>= 60 KG	61	28 (45.9)	15.31 (6.01, N.A.)	66	31 (47.0)	8.54 (4.73, 9.76)	0.658 (0.386, 1.120) 0.1910	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 18 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.6537
STAGE I	5	1 (20.0)	N.A. (2.17, N.A.)	5	2 (40.0)	9.53 (8.54, N.A.)	0.007 (<0.001, 6.581) 0.5203	
STAGE II	5	3 (60.0)	5.65 (0.53, N.A.)	5	2 (40.0)	N.A. (0.53, N.A.)	1.738 (0.217, 13.931) 0.8137	
STAGE III	31	14 (45.2)	11.96 (2.92, N.A.)	44	18 (40.9)	10.51 (5.03, 15.67)	0.610 (0.284, 1.309) 0.5856	
STAGE IV	114	57 (50.0)	8.38 (5.36, 15.34)	86	33 (38.4)	9.76 (5.26, N.A.)	1.088 (0.701, 1.688) 0.6217	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 19 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.7286
GX	11	6 (54.5)	1.87 (0.53, N.A.)	14	7 (50.0)	8.54 (2.83, N.A.)	0.596 (0.145, 2.456) 0.6220	
G1	8	4 (50.0)	4.63 (0.53, N.A.)	7	2 (28.6)	N.A. (4.17, N.A.)	2.214 (0.399, 12.297) 0.3244	
G2	58	28 (48.3)	11.96 (5.36, 20.83)	46	14 (30.4)	15.01 (5.68, N.A.)	0.960 (0.489, 1.884) 0.7199	
G3	27	13 (48.1)	9.72 (2.92, N.A.)	36	12 (33.3)	10.51 (9.53, N.A.)	1.038 (0.453, 2.382) 0.9761	
NOT OTHERWISE SPECIFIED	50	23 (46.0)	8.74 (2.99, N.A.)	37	20 (54.1)	5.26 (4.21, 9.13)	0.786 (0.428, 1.441) 0.4758	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 20 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.5581
UPPER THORACIC	35	21 (60.0)	6.14 (2.79, 12.48)	24	11 (45.8)	5.59 (4.21, N.A.)	0.951 (0.452, 2.003) 0.9649	
MIDDLE THORACIC	50	26 (52.0)	6.24 (2.89, 20.83)	50	18 (36.0)	15.01 (5.91, N.A.)	1.228 (0.651, 2.316) 0.3452	
LOWER THORACIC	59	25 (42.4)	15.31 (5.36, N.A.)	59	25 (42.4)	9.13 (4.30, 10.51)	0.714 (0.401, 1.270) 0.3361	
GASTROESOPHAGEAL JUNCTION	11	4 (36.4)	8.38 (1.15, N.A.)	7	1 (14.3)	N.A. (0.53, N.A.)	1.409 (0.141, 14.085) 0.5425	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 21 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.4140
RECURRENT - LOCO-REGIONAL	7	3 (42.9)	18.40 (0.53, N.A.)	12	6 (50.0)	8.54 (1.45, N.A.)	0.491 (0.073, 3.292) 0.5283	
RECURRENT - DISTANT	24	11 (45.8)	8.38 (2.10, N.A.)	27	8 (29.6)	10.51 (4.93, N.A.)	1.619 (0.626, 4.185) 0.4726	
DE NOVO METASTATIC	107	53 (49.5)	8.74 (5.13, 15.34)	78	29 (37.2)	9.76 (5.26, N.A.)	1.105 (0.695, 1.757) 0.5106	
UNRESECTABLE ADVANCED	18	9 (50.0)	11.96 (4.11, N.A.)	23	12 (52.2)	6.01 (2.86, N.A.)	0.507 (0.202, 1.273) 0.2422	
SMOKING STATUS								0.5023
CURRENT/FORMER	134	69 (51.5)	8.74 (5.65, 15.34)	109	45 (41.3)	9.13 (5.68, 11.14)	0.945 (0.641, 1.395) 0.9720	
NEVER/UNKNOWN	22	7 (31.8)	N.A. (2.99, N.A.)	31	10 (32.3)	15.01 (5.59, N.A.)	0.782 (0.287, 2.132) 0.9763	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 22 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.2427
CURRENT/FORMER	124	65 (52.4)	8.38 (5.65, 15.31)	115	44 (38.3)	9.53 (6.01, 15.67)	1.004 (0.676, 1.492) 0.5564	
NEVER/UNKNOWN	32	11 (34.4)	N.A. (2.99, N.A.)	25	11 (44.0)	5.26 (2.96, N.A.)	0.750 (0.322, 1.746) 0.5353	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.1947
<= 1	79	36 (45.6)	11.96 (6.01, 20.83)	67	29 (43.3)	9.13 (5.91, 15.67)	0.745 (0.448, 1.238) 0.4822	
>= 2	77	40 (51.9)	8.74 (2.99, 15.34)	73	26 (35.6)	10.51 (5.22, N.A.)	1.285 (0.775, 2.132) 0.2260	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 23 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.1896
< 1 YEAR	128	60 (46.9)	11.43 (6.11, 18.69)	111	45 (40.5)	9.13 (5.62, 15.67)	0.839 (0.563, 1.251) 0.6321	
1 - < 3 YEARS	23	14 (60.9)	2.92 (0.59, N.A.)	20	7 (35.0)	10.51 (0.95, N.A.)	1.362 (0.517, 3.587) 0.2605	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.5335
YES	36	17 (47.2)	8.38 (2.86, N.A.)	35	13 (37.1)	9.53 (5.03, N.A.)	1.241 (0.595, 2.589) 0.6539	
NO	120	59 (49.2)	9.72 (5.65, 18.40)	105	42 (40.0)	9.76 (5.62, 15.67)	0.926 (0.614, 1.397) 0.9645	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:32:59

Protocol: CA209648 Page 24 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.0444*
YES	24	13 (54.2)	5.65 (2.17, 19.38)	26	4 (15.4)	N.A. (5.22, N.A.)	2.856 (0.878, 9.284) 0.0352	
NO	132	63 (47.7)	9.72 (6.01, 18.69)	114	51 (44.7)	9.13 (5.62, 11.14)	0.820 (0.561, 1.199) 0.4781	
PD-L1 CPS I								0.7468
< 10	51	24 (47.1)	11.96 (2.89, 25.07)	51	19 (37.3)	9.76 (5.03, N.A.)	1.041 (0.558, 1.942) 0.8260	
>= 10	92	43 (46.7)	11.43 (6.01, 18.69)	87	35 (40.2)	10.51 (5.91, 15.67)	0.880 (0.554, 1.398) 0.9511	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 25 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.7373
< 5	28	13 (46.4)	5.13 (1.71, N.A.)	22	9 (40.9)	5.03 (3.84, N.A.)	1.092 (0.450, 2.649) 0.9033	
>= 5	115	54 (47.0)	11.43 (6.01, 18.69)	116	45 (38.8)	10.51 (5.91, 15.67)	0.919 (0.612, 1.381) 0.9634	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.7248
< 10%	54	25 (46.3)	11.96 (5.13, 25.07)	55	21 (38.2)	9.13 (5.03, N.A.)	0.867 (0.475, 1.583) 0.8396	
>= 10%	102	51 (50.0)	8.38 (5.36, 18.40)	85	34 (40.0)	10.51 (5.68, N.A.)	1.006 (0.643, 1.576) 0.6450	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 26 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=3)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.6808
< 5%	37	18 (48.6)	11.96 (4.01, 25.07)	39	14 (35.9)	9.76 (5.03, N.A.)	1.067 (0.516, 2.202) 0.6842	
>= 5%	119	58 (48.7)	8.74 (5.65, 18.40)	101	41 (40.6)	9.53 (5.68, N.A.)	0.911 (0.602, 1.379) 0.9861	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 27 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	58 (37.2)	18.40 (8.74, 25.07)	140	39 (27.9)	15.01 (8.67, N.A.)	0.994 (0.655, 1.510) 0.7252	
AGE								0.7362
< 65	93	32 (34.4)	18.40 (8.38, N.A.)	74	21 (28.4)	15.01 (8.67, N.A.)	0.875 (0.496, 1.543) 0.9736	
>= 65 AND < 75	55	20 (36.4)	18.69 (6.11, N.A.)	54	14 (25.9)	9.53 (6.47, N.A.)	1.272 (0.627, 2.579) 0.5983	
>= 75	8	6 (75.0)	7.29 (0.53, N.A.)	12	4 (33.3)	6.01 (3.84, N.A.)	0.635 (0.103, 3.921) 0.9721	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 28 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9987
MALE	129	50 (38.8)	18.40 (8.38, 25.07)	120	35 (29.2)	15.67 (8.67, N.A.)	0.978 (0.626, 1.528) 0.8000	
FEMALE	27	8 (29.6)	N.A. (4.21, N.A.)	20	4 (20.0)	15.01 (4.21, N.A.)	1.148 (0.343, 3.844) 0.7918	
RACE								0.9392
ASIAN	117	48 (41.0)	12.68 (7.29, 25.07)	103	34 (33.0)	9.76 (8.25, N.A.)	1.022 (0.652, 1.604) 0.8060	
NON-ASIAN	39	10 (25.6)	18.69 (8.38, N.A.)	37	5 (13.5)	15.01 (15.01, N.A.)	0.768 (0.238, 2.485) 0.6652	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 29 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.6717
J/K/T	91	39 (42.9)	15.34 (7.13, 25.07)	84	25 (29.8)	15.67 (8.64, N.A.)	1.122 (0.669, 1.883) 0.4147	
REST OF ASIA	25	8 (32.0)	12.68 (4.11, N.A.)	19	9 (47.4)	5.03 (1.45, N.A.)	0.529 (0.191, 1.470) 0.2010	
REST OF WORLD	40	11 (27.5)	18.69 (8.38, N.A.)	37	5 (13.5)	15.01 (15.01, N.A.)	0.822 (0.262, 2.576) 0.6179	
REGION								0.8417
ASIA	116	47 (40.5)	12.68 (7.29, 25.07)	103	34 (33.0)	9.76 (8.25, N.A.)	1.012 (0.644, 1.592) 0.8384	
NON-ASIA	40	11 (27.5)	18.69 (8.38, N.A.)	37	5 (13.5)	15.01 (15.01, N.A.)	0.822 (0.262, 2.576) 0.6179	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 30 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7749
0	71	37 (52.1)	9.72 (6.11, 18.40)	68	22 (32.4)	15.67 (8.25, N.A.)	1.057 (0.612, 1.825) 0.4181	
1	85	21 (24.7)	25.07 (18.69, N.A.)	70	16 (22.9)	15.01 (9.76, N.A.)	0.985 (0.503, 1.930) 0.8706	
WEIGHT								0.0965
< 60 KG	95	39 (41.1)	9.72 (6.14, 20.83)	74	18 (24.3)	15.01 (8.64, N.A.)	1.347 (0.762, 2.383) 0.1722	
>= 60 KG	61	19 (31.1)	25.07 (12.48, N.A.)	66	21 (31.8)	9.76 (6.01, N.A.)	0.658 (0.344, 1.259) 0.2764	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 31 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8144
STAGE I	5	1 (20.0)	N.A. (2.17, N.A.)	5	1 (20.0)	N.A. (9.53, N.A.)	<0.001 (<0.001, N.A.) 0.9372	
STAGE II	5	2 (40.0)	7.29 (3.84, N.A.)	5	2 (40.0)	N.A. (0.53, N.A.)	0.638 (0.086, 4.721) 0.6533	
STAGE III	31	11 (35.5)	18.40 (7.13, N.A.)	44	13 (29.5)	15.67 (6.47, N.A.)	0.674 (0.281, 1.613) 0.8269	
STAGE IV	114	43 (37.7)	15.34 (8.38, N.A.)	86	23 (26.7)	15.01 (8.64, N.A.)	1.159 (0.690, 1.948) 0.5908	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 32 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.6972
GX	11	5 (45.5)	8.08 (0.53, N.A.)	14	5 (35.7)	N.A. (3.75, N.A.)	1.348 (0.343, 5.299) 0.3581	
G1	8	3 (37.5)	N.A. (0.53, N.A.)	7	2 (28.6)	8.25 (5.62, N.A.)	1.410 (0.226, 8.795) 0.7318	
G2	58	21 (36.2)	19.38 (6.24, N.A.)	46	10 (21.7)	15.01 (15.01, N.A.)	0.942 (0.427, 2.077) 0.6559	
G3	27	11 (40.7)	15.34 (8.38, N.A.)	36	8 (22.2)	15.67 (9.53, N.A.)	1.168 (0.436, 3.129) 0.9436	
NOT OTHERWISE SPECIFIED	50	16 (32.0)	12.48 (7.13, N.A.)	37	14 (37.8)	6.47 (5.03, N.A.)	0.682 (0.330, 1.413) 0.3309	

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(1) KME of median time to event.
(2) Unstratified Cox proportional hazard model, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 33 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8267
UPPER THORACIC	35	17 (48.6)	8.08 (5.62, N.A.)	24	10 (41.7)	6.47 (4.93, N.A.)	0.792 (0.355, 1.769) 0.7675	
MIDDLE THORACIC	50	19 (38.0)	18.69 (6.24, N.A.)	50	11 (22.0)	15.01 (15.01, N.A.)	1.112 (0.511, 2.423) 0.4083	
LOWER THORACIC	59	20 (33.9)	19.38 (9.72, N.A.)	59	17 (28.8)	9.76 (8.64, N.A.)	0.871 (0.444, 1.709) 0.7023	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A. (2.17, N.A.)	7	1 (14.3)	N.A. (0.53, N.A.)	0.853 (0.033, 21.979) 0.7686	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 34 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5026
RECURRENT - LOCO-REGIONAL	7	2 (28.6)	18.40 (2.92, N.A.)	12	4 (33.3)	N.A. (5.03, N.A.)	0.104 (0.004, 2.983) 0.4707	
RECURRENT - DISTANT	24	9 (37.5)	8.38 (2.79, N.A.)	27	6 (22.2)	N.A. (4.93, N.A.)	1.537 (0.526, 4.487) 0.5046	
DE NOVO METASTATIC	107	39 (36.4)	15.34 (8.08, N.A.)	78	20 (25.6)	15.01 (8.64, N.A.)	1.160 (0.669, 2.011) 0.5226	
UNRESECTABLE ADVANCED	18	8 (44.4)	25.07 (3.84, N.A.)	23	9 (39.1)	8.67 (5.59, N.A.)	0.673 (0.248, 1.824) 0.5889	
SMOKING STATUS								0.1442
CURRENT/FORMER	134	53 (39.6)	15.34 (8.38, 20.83)	109	30 (27.5)	15.67 (8.67, N.A.)	1.083 (0.682, 1.720) 0.6207	
NEVER/UNKNOWN	22	5 (22.7)	N.A. (4.21, N.A.)	31	9 (29.0)	15.01 (5.59, N.A.)	0.544 (0.175, 1.694) 0.6301	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:32:59

Protocol: CA209648 Page 35 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.1068
CURRENT/FORMER	124	52 (41.9)	15.34 (7.13, 20.83)	115	32 (27.8)	15.67 (8.67, N.A.)	1.144 (0.728, 1.797) 0.3406	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (12.68, N.A.)	25	7 (28.0)	15.01 (4.21, N.A.)	0.511 (0.168, 1.551) 0.2757	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.7242
<= 1	79	28 (35.4)	19.38 (8.38, N.A.)	67	19 (28.4)	15.67 (8.64, N.A.)	0.920 (0.504, 1.681) 0.9626	
>= 2	77	30 (39.0)	15.34 (5.36, N.A.)	73	20 (27.4)	15.01 (15.01, N.A.)	1.183 (0.661, 2.116) 0.4051	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 36 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2624
< 1 YEAR	128	45 (35.2)	18.69 (9.72, N.A.)	111	33 (29.7)	15.01 (8.25, 15.67)	0.855 (0.539, 1.358) 0.6530	
1 - < 3 YEARS	23	12 (52.2)	7.13 (1.48, N.A.)	20	5 (25.0)	N.A. (1.45, N.A.)	1.504 (0.494, 4.576) 0.2436	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.5479
YES	36	13 (36.1)	19.38 (4.21, N.A.)	35	9 (25.7)	N.A. (6.47, N.A.)	1.327 (0.557, 3.163) 0.5804	
NO	120	45 (37.5)	18.40 (8.08, 25.07)	105	30 (28.6)	15.01 (8.64, N.A.)	0.940 (0.584, 1.516) 0.9326	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 37 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1254
YES	24	11 (45.8)	7.29 (2.89, 19.38)	26	3 (11.5)	N.A.	2.592 (0.669, 10.050) 0.0654	
NO	132	47 (35.6)	18.69 (9.72, N.A.)	114	36 (31.6)	9.76 (8.64, 15.67)	0.879 (0.563, 1.373) 0.6690	
PD-L1 CPS I								0.5976
< 10	51	18 (35.3)	20.83 (5.75, N.A.)	51	12 (23.5)	9.76 (5.68, N.A.)	1.118 (0.527, 2.371) 0.6835	
>= 10	92	31 (33.7)	18.69 (8.38, N.A.)	87	26 (29.9)	15.01 (8.64, N.A.)	0.858 (0.499, 1.476) 0.7727	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 38 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.9578
< 5	28	11 (39.3)	20.83 (3.48, N.A.)	22	8 (36.4)	9.76 (3.84, N.A.)	0.900 (0.344, 2.355) 0.8073	
>= 5	115	38 (33.0)	18.69 (12.48, N.A.)	116	30 (25.9)	15.01 (8.67, N.A.)	0.960 (0.588, 1.568) 0.9114	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5333
< 10%	54	18 (33.3)	25.07 (8.38, N.A.)	55	15 (27.3)	15.01 (8.67, N.A.)	0.816 (0.401, 1.660) 0.7736	
>= 10%	102	40 (39.2)	12.68 (8.08, 19.38)	85	24 (28.2)	15.67 (8.64, N.A.)	1.087 (0.644, 1.833) 0.5324	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 39 of 39

FWB: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FWB (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.8702
< 5%	37	13 (35.1)	20.83 (5.75, N.A.)	39	11 (28.2)	9.76 (8.67, N.A.)	0.905 (0.391, 2.097) 0.9835	
>= 5%	119	45 (37.8)	15.34 (8.08, N.A.)	101	28 (27.7)	15.01 (8.64, N.A.)	1.009 (0.620, 1.642) 0.7235	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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3.28 Subgruppenanalysen – ECS (MID = 11)

Protocol: CA209648 Page 1 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	34 (21.8)	N.A. (32.69, N.A.)	142	30 (21.1)	N.A. (18.14, N.A.)	0.766 (0.463, 1.265) 0.3071	
AGE								0.4580
< 65	93	14 (15.1)	N.A. (28.91, N.A.)	74	14 (18.9)	N.A. (13.60, N.A.)	0.629 (0.295, 1.337) 0.3325	
>= 65 AND < 75	55	17 (30.9)	N.A. (19.02, N.A.)	56	12 (21.4)	20.50 (11.53, N.A.)	1.095 (0.512, 2.343) 0.9878	
>= 75	8	3 (37.5)	33.41 (1.05, N.A.)	12	4 (33.3)	N.A. (2.20, N.A.)	0.358 (0.037, 3.428) 0.2575	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 2 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4877
MALE	129	32 (24.8)	N.A. (28.91, N.A.)	121	27 (22.3)	N.A. (14.42, N.A.)	0.807 (0.477, 1.365) 0.4936	
FEMALE	27	2 (7.4)	N.A.	21	3 (14.3)	N.A. (5.55, N.A.)	0.419 (0.067, 2.601) 0.3445	
RACE								0.0733
ASIAN	117	32 (27.4)	N.A. (28.91, N.A.)	103	23 (22.3)	N.A. (18.14, N.A.)	0.944 (0.546, 1.631) 0.8684	
NON-ASIAN	39	2 (5.1)	N.A.	39	7 (17.9)	13.60 (7.59, N.A.)	0.204 (0.042, 1.002) 0.0285	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 3 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.1292
J/K/T	91	25 (27.5)	N.A. (28.91, N.A.)	84	19 (22.6)	N.A. (18.33, N.A.)	0.881 (0.477, 1.626) 0.7610	
REST OF ASIA	25	7 (28.0)	N.A. (4.21, N.A.)	19	4 (21.1)	18.14 (3.38, N.A.)	1.264 (0.348, 4.585) 0.8180	
REST OF WORLD	40	2 (5.0)	N.A.	39	7 (17.9)	13.60 (7.59, N.A.)	0.186 (0.038, 0.919) 0.0234	
REGION								0.0547
ASIA	116	32 (27.6)	N.A. (28.91, N.A.)	103	23 (22.3)	N.A. (18.14, N.A.)	0.962 (0.557, 1.661) 0.9085	
NON-ASIA	40	2 (5.0)	N.A.	39	7 (17.9)	13.60 (7.59, N.A.)	0.186 (0.038, 0.919) 0.0234	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 4 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9940
0	71	21 (29.6)	32.69 (21.52, N.A.)	69	18 (26.1)	N.A. (18.14, N.A.)	0.739 (0.388, 1.405) 0.4844	
1	85	13 (15.3)	N.A.	71	11 (15.5)	N.A. (13.60, N.A.)	0.888 (0.392, 2.010) 0.7342	
WEIGHT								0.1575
< 60 KG	95	23 (24.2)	33.41 (28.91, N.A.)	75	13 (17.3)	20.50 (18.14, N.A.)	1.019 (0.505, 2.054) 0.9419	
>= 60 KG	61	11 (18.0)	N.A. (32.69, N.A.)	67	17 (25.4)	N.A. (11.53, N.A.)	0.514 (0.237, 1.114) 0.0965	

Oct 2021 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.
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(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8388
STAGE I	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE II	5	1 (20.0)	N.A. (2.76, N.A.)	5	0	N.E.	N.E. 0.5271	
STAGE III	31	7 (22.6)	28.91 (8.31, N.A.)	45	9 (20.0)	N.A. (8.44, N.A.)	1.144 (0.413, 3.172) 0.8528	
STAGE IV	114	25 (21.9)	N.A. (32.69, N.A.)	87	21 (24.1)	20.50 (11.53, N.A.)	0.642 (0.353, 1.168) 0.1625	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 6 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2979
GX	11	4 (36.4)	N.A. (0.53, N.A.)	14	0	N.E.	N.E. 0.0098	
G1	8	1 (12.5)	N.A. (32.69, N.A.)	7	2 (28.6)	N.A. (0.49, N.A.)	<0.001 (<0.001, N.A.) 0.1159	
G2	58	11 (19.0)	N.A. (28.91, N.A.)	48	7 (14.6)	N.A.	0.934 (0.357, 2.443) 0.9420	
G3	27	8 (29.6)	33.41 (19.02, N.A.)	36	7 (19.4)	N.A. (9.76, N.A.)	1.204 (0.411, 3.530) 0.9422	
NOT OTHERWISE SPECIFIED	50	10 (20.0)	N.A. (21.52, N.A.)	37	14 (37.8)	13.60 (5.78, 20.50)	0.363 (0.157, 0.837) 0.0236	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 7 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9818
UPPER THORACIC	35	6 (17.1)	N.A. (19.84, N.A.)	24	6 (25.0)	N.A. (5.55, N.A.)	0.633 (0.202, 1.984) 0.3304	
MIDDLE THORACIC	50	12 (24.0)	32.69 (32.69, N.A.)	51	11 (21.6)	18.33 (13.60, N.A.)	0.755 (0.318, 1.789) 0.6635	
LOWER THORACIC	59	14 (23.7)	N.A. (28.91, N.A.)	59	13 (22.0)	N.A. (9.76, N.A.)	0.767 (0.354, 1.664) 0.4554	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (2.76, N.A.)	8	0	N.E.	N.E. 0.3545	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:07:51

Protocol: CA209648 Page 8 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.4025
RECURRENT - LOCO-REGIONAL	7	2 (28.6)	N.A. (2.76, N.A.)	12	3 (25.0)	N.A. (5.03, N.A.)	1.132 (0.150, 8.543) 0.8117	
RECURRENT - DISTANT	24	5 (20.8)	28.91 (8.31, N.A.)	27	2 (7.4)	N.A.	2.851 (0.492, 16.529) 0.3315	
DE NOVO METASTATIC	107	23 (21.5)	N.A. (32.69, N.A.)	79	19 (24.1)	20.50 (9.76, N.A.)	0.641 (0.343, 1.196) 0.1808	
UNRESECTABLE ADVANCED	18	4 (22.2)	N.A. (8.11, N.A.)	24	6 (25.0)	18.33 (6.01, N.A.)	0.417 (0.107, 1.620) 0.2459	
SMOKING STATUS								0.8637
CURRENT/FORMER	134	30 (22.4)	N.A. (28.91, N.A.)	109	24 (22.0)	20.50 (14.42, N.A.)	0.721 (0.414, 1.255) 0.2393	
NEVER/UNKNOWN	22	4 (18.2)	N.A. (4.11, N.A.)	33	6 (18.2)	N.A. (11.53, N.A.)	0.809 (0.224, 2.920) 0.9236	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:07:51

Protocol: CA209648 Page 9 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.2054
CURRENT/FORMER	124	28 (22.6)	N.A. (28.91, N.A.)	116	22 (19.0)	N.A. (18.33, N.A.)	0.906 (0.513, 1.600) 0.7442	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (19.84, N.A.)	26	8 (30.8)	13.60 (5.55, N.A.)	0.367 (0.116, 1.161) 0.0801	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.2789
<= 1	79	15 (19.0)	N.A. (28.91, N.A.)	68	16 (23.5)	N.A. (13.60, N.A.)	0.604 (0.295, 1.233) 0.1354	
>= 2	77	19 (24.7)	33.41 (21.52, N.A.)	74	14 (18.9)	20.50 (18.14, N.A.)	0.931 (0.453, 1.916) 0.9748	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:07:51

Protocol: CA209648 Page 10 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.1890
< 1 YEAR	128	27 (21.1)	N.A. (32.69, N.A.)	113	26 (23.0)	20.50 (13.60, N.A.)	0.627 (0.360, 1.093) 0.1121	
1 - < 3 YEARS	23	7 (30.4)	28.91 (2.92, N.A.)	20	4 (20.0)	N.A. (5.03, N.A.)	2.390 (0.565, 10.117) 0.6261	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.1979
YES	36	7 (19.4)	28.91 (19.84, N.A.)	36	4 (11.1)	N.A.	1.560 (0.436, 5.584) 0.5972	
NO	120	27 (22.5)	N.A. (32.69, N.A.)	106	26 (24.5)	18.33 (13.60, N.A.)	0.641 (0.369, 1.115) 0.1504	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:07:51

Protocol: CA209648 Page 11 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1900
YES	24	4 (16.7)	28.91 (7.13, N.A.)	26	2 (7.7)	N.A. (7.95, N.A.)	3.479 (0.479, 25.280) 0.5695	
NO	132	30 (22.7)	N.A. (32.69, N.A.)	116	28 (24.1)	20.50 (14.42, N.A.)	0.683 (0.403, 1.158) 0.1880	
PD-L1 CPS I								0.5471
< 10	51	7 (13.7)	N.A. (21.52, N.A.)	52	11 (21.2)	N.A. (8.44, N.A.)	0.552 (0.213, 1.430) 0.1641	
>= 10	92	21 (22.8)	N.A. (32.69, N.A.)	88	19 (21.6)	20.50 (14.42, N.A.)	0.747 (0.392, 1.424) 0.3914	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:07:51

Protocol: CA209648 Page 12 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.4162
< 5	28	3 (10.7)	N.A.	22	6 (27.3)	N.A.	0.489	
						(5.03, N.A.)	(0.122, 1.962)	
							0.2683	
>= 5	115	25 (21.7)	N.A.	118	24 (20.3)	20.50	0.733	
			(32.69, N.A.)			(18.14, N.A.)	(0.411, 1.306)	
							0.2885	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.1101
< 10%	54	10 (18.5)	N.A.	56	15 (26.8)	18.14	0.463	
			(21.52, N.A.)			(9.76, N.A.)	(0.206, 1.042)	
							0.0762	
>= 10%	102	24 (23.5)	N.A.	86	15 (17.4)	N.A.	1.095	
			(28.91, N.A.)			(18.33, N.A.)	(0.563, 2.129)	
							0.8373	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:07:51

Protocol: CA209648 Page 13 of 13

FACT-ECS: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-ECS (MID=11)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.1220
< 5%	37	7 (18.9)	N.A. (21.52, N.A.)	40	14 (35.0)	18.14 (8.44, N.A.)	0.435 (0.175, 1.083) 0.0606	
>= 5%	119	27 (22.7)	N.A. (28.91, N.A.)	102	16 (15.7)	N.A. (18.33, N.A.)	1.059 (0.560, 2.000) 0.8148	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 01APR2022:19:07:51

3.29 Subgruppenanalysen – FACT-G7 Gesamtscore (MID = 5)

Protocol: CA209648 Page 1 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	156	52 (33.3)	27.24 (20.70, N.A.)	141	39 (27.7)	16.56 (12.88, N.A.)	0.818 (0.535, 1.251) 0.4529	
AGE								0.4813
< 65	93	31 (33.3)	25.07 (13.77, N.A.)	74	19 (25.7)	N.A. (8.90, N.A.)	0.948 (0.531, 1.693) 0.9660	
>= 65 AND < 75	55	14 (25.5)	N.A. (24.90, N.A.)	55	16 (29.1)	16.56 (11.53, 27.20)	0.562 (0.267, 1.181) 0.1160	
>= 75	8	7 (87.5)	12.65 (0.53, N.A.)	12	4 (33.3)	20.07 (6.01, N.A.)	0.352 (0.041, 3.024) 0.8183	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 2 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6556
MALE	129	46 (35.7)	24.90 (18.00, 32.69)	121	36 (29.8)	15.67 (11.53, N.A.)	0.771 (0.493, 1.207) 0.4120	
FEMALE	27	6 (22.2)	N.A. (5.36, N.A.)	20	3 (15.0)	N.A. (12.88, N.A.)	1.163 (0.289, 4.684) 0.8292	
RACE								0.9903
ASIAN	117	46 (39.3)	24.90 (16.59, 32.69)	103	35 (34.0)	15.67 (12.85, 27.20)	0.822 (0.525, 1.288) 0.4187	
NON-ASIAN	39	6 (15.4)	N.A.	38	4 (10.5)	N.A. (7.49, N.A.)	0.761 (0.202, 2.859) 0.6709	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 3 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9933
J/K/T	91	38 (41.8)	24.90 (17.87, N.A.)	84	29 (34.5)	14.46 (11.53, N.A.)	0.855 (0.521, 1.402) 0.5828	
REST OF ASIA	25	8 (32.0)	13.77 (8.74, N.A.)	19	6 (31.6)	16.56 (3.38, N.A.)	0.789 (0.264, 2.359) 0.6684	
REST OF WORLD	40	6 (15.0)	N.A.	38	4 (10.5)	N.A. (7.49, N.A.)	0.728 (0.195, 2.722) 0.7215	
REGION								0.9113
ASIA	116	46 (39.7)	23.59 (16.59, 32.69)	103	35 (34.0)	15.67 (12.85, 27.20)	0.836 (0.534, 1.309) 0.4634	
NON-ASIA	40	6 (15.0)	N.A.	38	4 (10.5)	N.A. (7.49, N.A.)	0.728 (0.195, 2.722) 0.7215	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 4 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.5819
0	71	33 (46.5)	20.83 (13.70, 32.69)	68	23 (33.8)	15.67 (11.53, N.A.)	0.876 (0.510, 1.503) 0.8673	
1	85	19 (22.4)	N.A. (24.90, N.A.)	71	16 (22.5)	16.56 (12.85, N.A.)	0.706 (0.349, 1.426) 0.3071	
WEIGHT								0.1578
< 60 KG	95	35 (36.8)	21.52 (13.70, N.A.)	74	17 (23.0)	18.14 (12.88, N.A.)	1.022 (0.563, 1.854) 0.8346	
>= 60 KG	61	17 (27.9)	32.69 (25.07, N.A.)	67	22 (32.8)	14.46 (11.04, N.A.)	0.609 (0.320, 1.159) 0.1584	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
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Protocol: CA209648 Page 5 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9640
STAGE I	5	2 (40.0)	N.A. (2.17, N.A.)	5	2 (40.0)	N.A. (8.90, N.A.)	0.366 (0.031, 4.375) 0.7649	
STAGE II	5	2 (40.0)	15.44 (7.29, N.A.)	5	1 (20.0)	N.A. (0.53, N.A.)	<0.001 (<0.001, N.A.) 0.7456	
STAGE III	31	11 (35.5)	32.33 (8.11, N.A.)	45	12 (26.7)	16.56 (12.85, N.A.)	0.989 (0.430, 2.275) 0.8011	
STAGE IV	114	36 (31.6)	27.24 (20.70, N.A.)	86	24 (27.9)	18.14 (11.53, N.A.)	0.797 (0.471, 1.351) 0.4015	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 6 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2391
GX	11	4 (36.4)	16.59 (1.61, N.A.)	14	5 (35.7)	N.A. (2.96, N.A.)	0.806 (0.174, 3.741) 0.6855	
G1	8	4 (50.0)	22.83 (0.53, N.A.)	7	2 (28.6)	8.25 (4.14, N.A.)	0.875 (0.116, 6.577) 0.8781	
G2	58	22 (37.9)	25.07 (13.77, N.A.)	47	5 (10.6)	N.A. (12.88, N.A.)	2.149 (0.806, 5.731) 0.0862	
G3	27	6 (22.2)	N.A. (18.00, N.A.)	36	12 (33.3)	15.67 (11.04, N.A.)	0.437 (0.157, 1.216) 0.0816	
NOT OTHERWISE SPECIFIED	50	15 (30.0)	N.A. (9.79, N.A.)	37	15 (40.5)	12.85 (5.78, 20.07)	0.502 (0.238, 1.059) 0.1318	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 7 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.4501
UPPER THORACIC	35	11 (31.4)	N.A. (12.48, N.A.)	24	10 (41.7)	18.14 (5.03, N.A.)	0.612 (0.258, 1.450) 0.2758	
MIDDLE THORACIC	50	21 (42.0)	23.59 (7.29, 32.69)	50	9 (18.0)	15.67 (12.88, N.A.)	1.276 (0.554, 2.939) 0.3379	
LOWER THORACIC	59	19 (32.2)	32.33 (18.00, N.A.)	59	19 (32.2)	16.56 (7.49, N.A.)	0.730 (0.383, 1.394) 0.3355	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (1.22, N.A.)	8	1 (12.5)	N.A. (0.53, N.A.)	0.644 (0.037, 11.343) 0.8995	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 8 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3465
RECURRENT - LOCO-REGIONAL	7	1 (14.3)	N.A. (13.70, N.A.)	12	3 (25.0)	N.A. (5.03, N.A.)	0.205 (0.009, 4.455) 0.5875	
RECURRENT - DISTANT	24	11 (45.8)	12.98 (2.79, 32.33)	27	7 (25.9)	16.56 (8.90, N.A.)	1.742 (0.612, 4.959) 0.6313	
DE NOVO METASTATIC	107	33 (30.8)	32.69 (18.00, N.A.)	78	21 (26.9)	18.14 (12.88, N.A.)	0.812 (0.466, 1.416) 0.5346	
UNRESECTABLE ADVANCED	18	7 (38.9)	25.07 (6.93, N.A.)	24	8 (33.3)	14.46 (6.01, N.A.)	0.520 (0.173, 1.561) 0.3104	
SMOKING STATUS								0.3924
CURRENT/FORMER	134	45 (33.6)	25.07 (20.70, N.A.)	109	33 (30.3)	15.67 (11.04, 27.20)	0.709 (0.446, 1.127) 0.1874	
NEVER/UNKNOWN	22	7 (31.8)	N.A. (5.36, N.A.)	32	6 (18.8)	N.A. (11.53, N.A.)	1.283 (0.419, 3.928) 0.5185	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 9 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.3181
CURRENT/FORMER	124	45 (36.3)	25.07 (20.70, N.A.)	116	33 (28.4)	16.56 (12.88, N.A.)	0.906 (0.574, 1.431) 0.7608	
NEVER/UNKNOWN	32	7 (21.9)	N.A. (12.98, N.A.)	25	6 (24.0)	18.14 (4.96, N.A.)	0.450 (0.138, 1.466) 0.2403	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.1103
<= 1	79	23 (29.1)	32.33 (20.83, N.A.)	68	21 (30.9)	14.46 (8.90, N.A.)	0.551 (0.301, 1.010) 0.0519	
>= 2	77	29 (37.7)	21.52 (12.48, N.A.)	73	18 (24.7)	18.14 (12.85, N.A.)	1.168 (0.640, 2.132) 0.4442	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 10 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2361
< 1 YEAR	128	40 (31.3)	32.69 (20.83, N.A.)	112	32 (28.6)	15.67 (12.85, N.A.)	0.706 (0.439, 1.135) 0.1910	
1 - < 3 YEARS	23	9 (39.1)	13.70 (2.92, N.A.)	20	5 (25.0)	20.07 (8.90, N.A.)	1.296 (0.417, 4.029) 0.5048	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4161
YES	36	13 (36.1)	23.59 (12.98, N.A.)	36	10 (27.8)	20.07 (11.04, N.A.)	1.073 (0.454, 2.539) 0.9169	
NO	120	39 (32.5)	27.24 (20.70, N.A.)	105	29 (27.6)	15.67 (12.88, N.A.)	0.780 (0.477, 1.275) 0.4370	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 11 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.0372*
YES	24	9 (37.5)	13.70 (5.55, N.A.)	26	1 (3.8)	N.A. (5.03, N.A.)	5.556 (0.667, 46.312) 0.0574	
NO	132	43 (32.6)	27.24 (20.83, N.A.)	115	38 (33.0)	15.67 (12.85, 27.20)	0.688 (0.441, 1.073) 0.1214	
PD-L1 CPS I								0.0610
< 10	51	18 (35.3)	21.52 (9.79, N.A.)	51	10 (19.6)	20.07 (7.49, N.A.)	1.641 (0.740, 3.638) 0.2855	
>= 10	92	30 (32.6)	32.33 (20.70, N.A.)	88	28 (31.8)	15.67 (12.88, N.A.)	0.626 (0.365, 1.076) 0.1292	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 12 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.2438
< 5	28	11 (39.3)	20.83 (3.55, N.A.)	22	7 (31.8)	12.85 (7.06, N.A.)	1.664 (0.611, 4.532) 0.3192	
>= 5	115	37 (32.2)	32.33 (20.70, N.A.)	117	31 (26.5)	16.56 (14.42, N.A.)	0.730 (0.445, 1.197) 0.2835	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3337
< 10%	54	18 (33.3)	24.90 (13.70, N.A.)	55	12 (21.8)	27.20 (12.85, N.A.)	1.154 (0.553, 2.409) 0.6937	
>= 10%	102	34 (33.3)	32.33 (17.87, N.A.)	86	27 (31.4)	15.67 (11.53, N.A.)	0.705 (0.417, 1.192) 0.2531	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

Protocol: CA209648 Page 13 of 13

FACT-G7: Time to Definitive Deterioration, Subgroup Analyses
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

PRO Scale: FACT-G7 (MID=5)

Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2485
< 5%	37	13 (35.1)	24.90 (20.83, N.A.)	39	10 (25.6)	27.20 (7.49, N.A.)	1.360 (0.588, 3.148) 0.6414	
>= 5%	119	39 (32.8)	32.33 (17.87, N.A.)	102	29 (28.4)	15.67 (11.53, N.A.)	0.707 (0.429, 1.165) 0.2737	

Oct 2021 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, with baseline PRO score as a covariate. HR is Nivo+Ipi over Chemo.
(3) Unstratified Log-rank Test. (4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between treatment and the subgroup, with baseline PRO score as a covariate. (5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
N is the number of randomized subjects with non missing baseline assessment.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-tfdsubfact-ebr503.sas 02MAR2022:11:31:20

3.30 Zusatzanalyse – Mittlere Änderung des FACT-E Gesamtscores während der Behandlung (MMRM)

Protocol: CA209648 Page 1 of 1

FACT-E: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
FACT Domain	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
FACT-E TOTAL SCORE	143	123.3 (24.4)	2.47 (-0.73, 5.67)	130	119.4 (22.6)	1.09 (-2.55, 4.73)	1.38 (-3.47, 6.23) 0.5743	0.07 (-0.17, 0.31)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:50:55

3.31 Zusatzanalyse – Mittlere Änderung des FACT-G Gesamtscores während der Behandlung (MMRM)

Protocol: CA209648 Page 1 of 1

FACT-G: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
FACT Domain	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
FACT-G TOTAL SCORE	143	77.8 (15.6)	0.12 (-1.82, 2.06)	130	74.3 (14.9)	-0.87 (-3.06, 1.33)	0.99 (-1.94, 3.93) 0.5062	0.08 (-0.16, 0.32)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:50:28

3.32 Zusatzanalyse – Mittlere Änderung der Subskala PWB während der Behandlung (MMRM)

Protocol: CA209648 Page 1 of 1

PWB: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

FACT Domain	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
PWB SCORE	143	22.0 (5.0)	0.09 (-0.57, 0.75)	131	21.6 (4.7)	-1.74 (-2.51, -0.98)	1.83 (0.82, 2.85) 0.0005	0.43 (0.19, 0.67)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:49:30

3.33 Zusatzanalyse – Mittlere Änderung der Subskala SWB während der Behandlung (MMRM)

Protocol: CA209648 Page 1 of 1

SWB: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

FACT Domain	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
SWB SCORE	143	21.0 (5.5)	-0.89 (-1.67, -0.12)	131	19.6 (6.4)	0.08 (-0.79, 0.96)	-0.98 (-2.15, 0.19) 0.1012	-0.20 (-0.43, 0.04)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:49:45

3.34 Zusatzanalyse – Mittlere Änderung der Subskala EWB während der Behandlung (MMRM)

Protocol: CA209648 Page 1 of 1

EWB: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

FACT Domain	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
EWB SCORE	143	17.7 (4.4)	1.15 (0.64, 1.66)	131	17.2 (4.9)	0.65 (0.07, 1.22)	0.50 (-0.26, 1.27) 0.1953	0.16 (-0.08, 0.39)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:49:59

3.35 Zusatzanalyse – Mittlere Änderung der Subskala FWB während der Behandlung (MMRM)

Protocol: CA209648 Page 1 of 1

FWB: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

FACT Domain	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
FWB SCORE	143	17.1 (6.3)	0.07 (-0.76, 0.89)	130	15.9 (6.5)	-0.05 (-0.98, 0.88)	0.12 (-1.13, 1.36) 0.8548	0.02 (-0.22, 0.26)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:50:14

3.36 Zusatzanalyse – Mittlere Änderung der ECS während der Behandlung (MMRM)

Protocol: CA209648 Page 1 of 1

FACT-ECS: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

FACT Domain	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
FACT-ECS TOTAL SCORE	143	45.5 (12.0)	2.20 (0.60, 3.81)	132	45.3 (10.9)	1.66 (-0.14, 3.46)	0.55 (-1.86, 2.96) 0.6554	0.05 (-0.18, 0.29)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:50:42

3.37 Zusatzanalyse – Mittlere Änderung des FACT-G7 Gesamtscores während der Behandlung (MMRM)

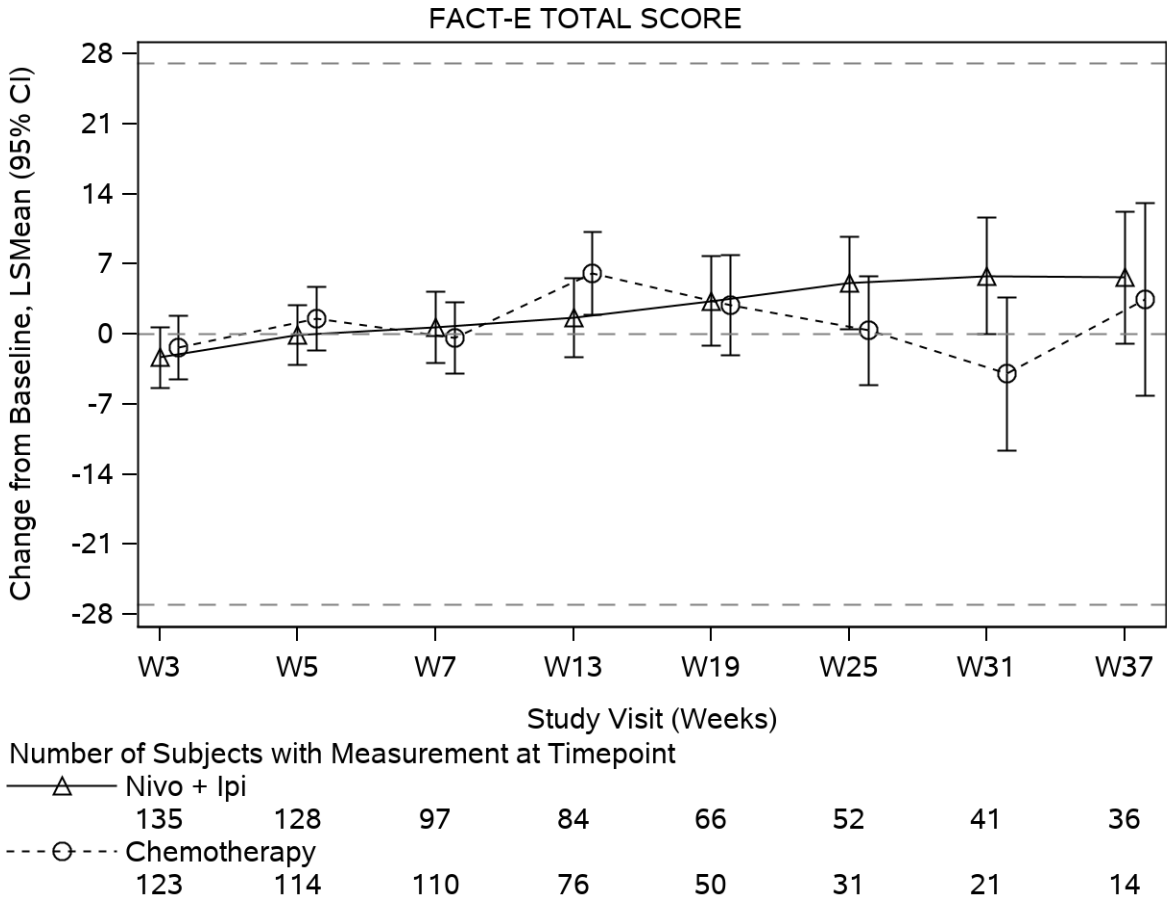
Protocol: CA209648 Page 1 of 1

FACT-G7: Mixed Model Repeated Measures
All Randomized Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

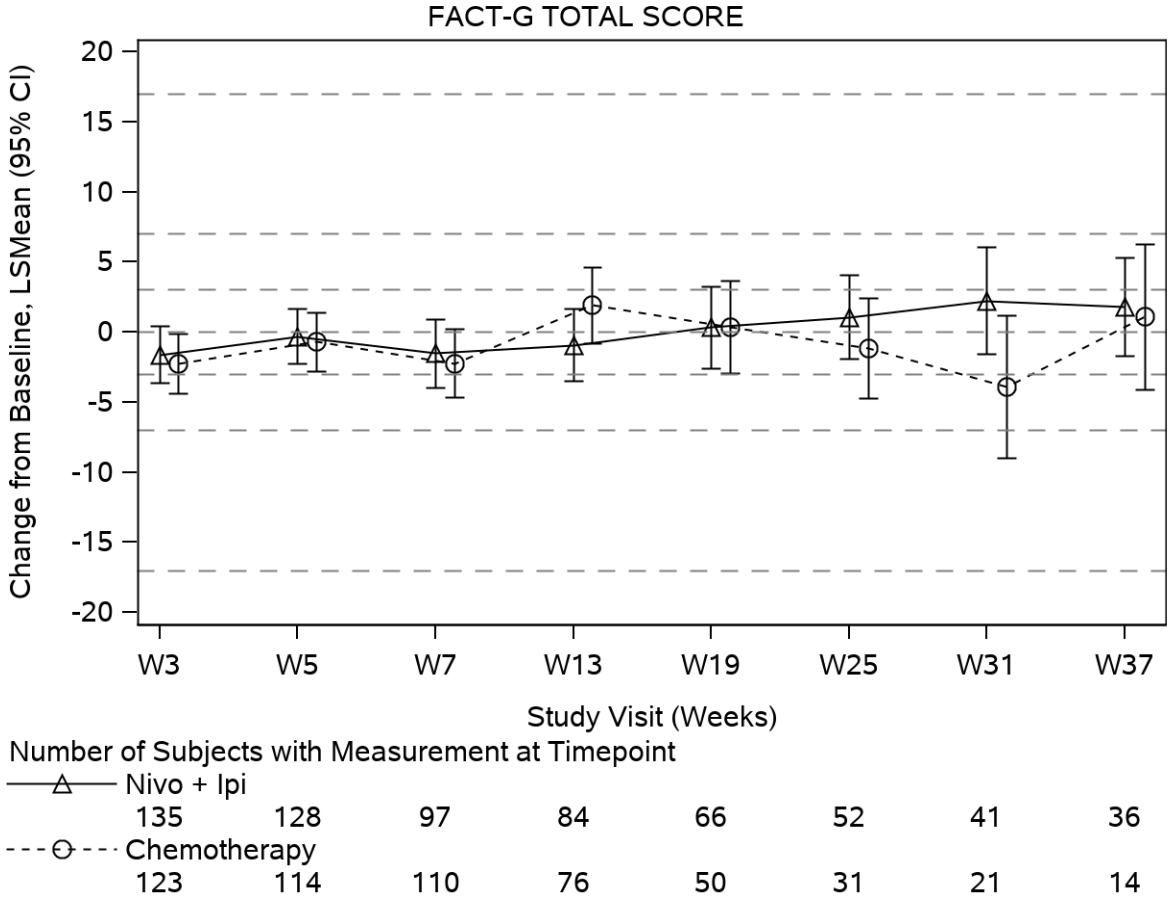
	Nivo + Ipi (N = 158)			Chemotherapy (N = 157)			Nivo + Ipi vs. Chemotherapy	
FACT Domain	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	N (1)	Baseline Mean (SD)	Change from Baseline: LS Mean (95% CI) (3)	Difference in Mean Change (95% CI) P-value (2) (3)	SMD as Hedges' g (95% CI)
FACT-G7 TOTAL SCORE	143	19.5 (5.2)	0.62 (0.02, 1.21)	131	18.5 (4.7)	-0.23 (-0.92, 0.45)	0.85 (-0.06, 1.76) 0.0673	0.22 (-0.02, 0.46)

Oct 2021 DBL. NE = Not estimated. SMD = standardized mean difference.
(1) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-trtment assessment.
(2) Positive difference favors treatment arm, negative difference favors Chemo.
(3) Estimates are based on a MMRM, with change from baseline as the primary dependent variable, treatment, visit week, stratification factors and trt*visit week interaction as fixed effects, baseline PRO score as covariate, and visit week as repeated measure. Models run using an UN covariance matrix whenever possible. Otherwise, if a model failed to converge, CS was used. If model failed to converge with CS, then N.A. should be displayed.
Only the on-treatment timepoints with 10 subjects or more in each treatment group are included in the analysis.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-sy-mmrm-ebr503.sas 14MAR2022:08:51:11

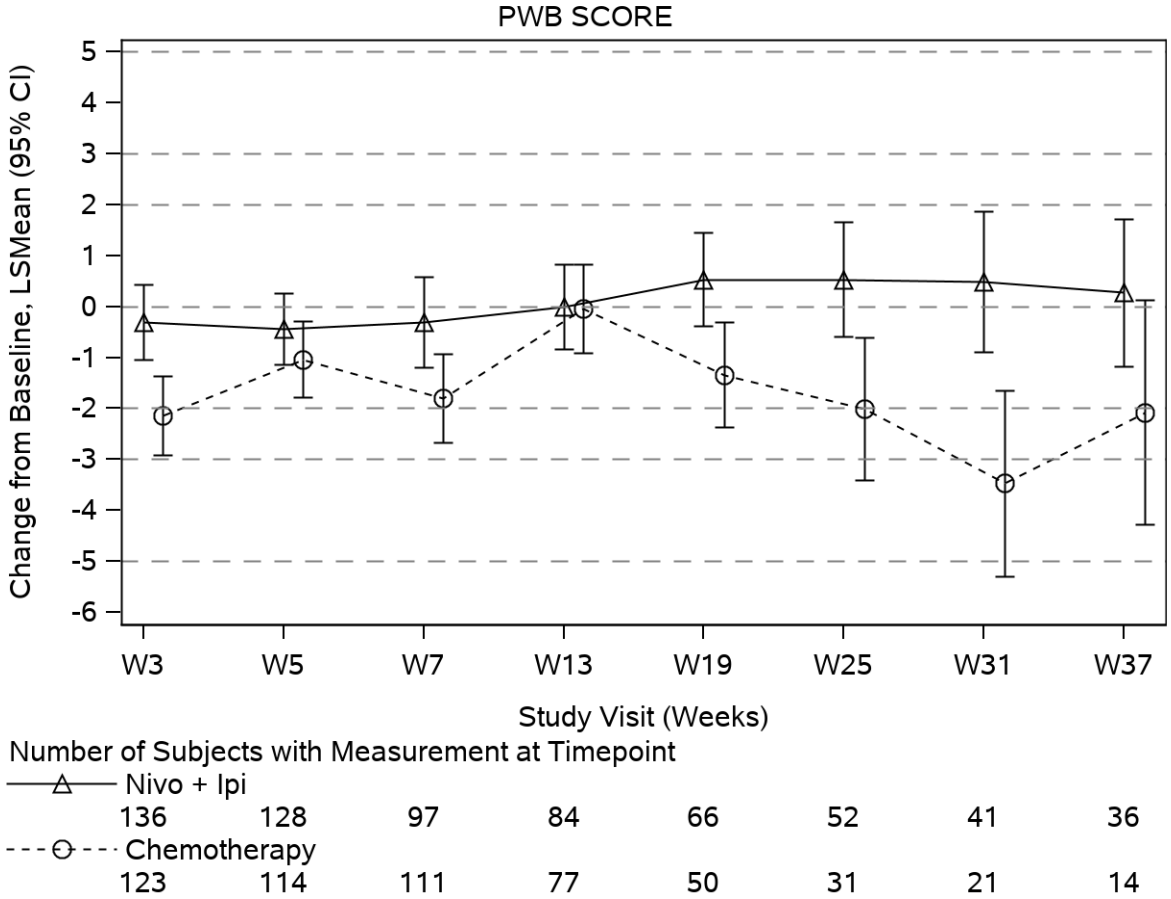
3.38 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung des FACT-E Gesamtscores im Behandlungsverlauf (MMRM)



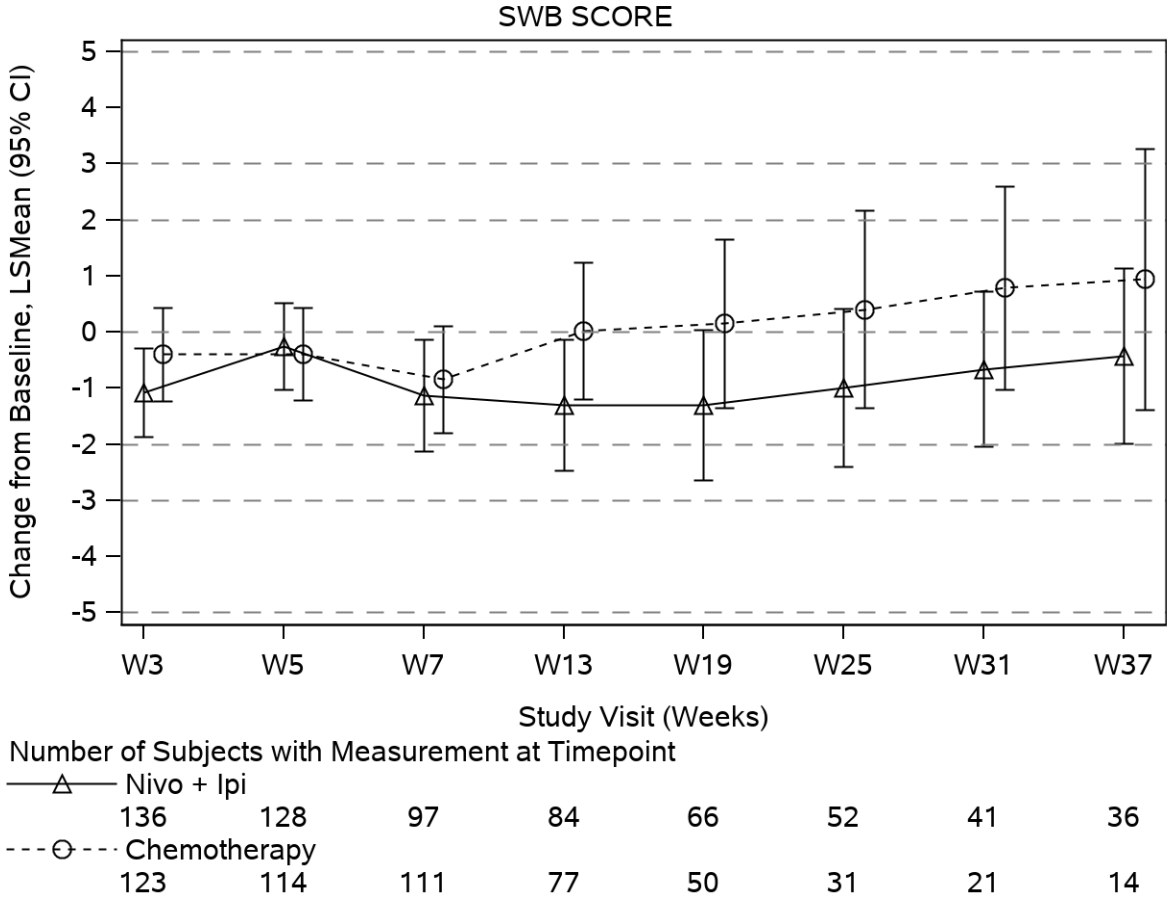
3.39 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung des FACT-G Gesamtscore im Behandlungsverlauf (MMRM)



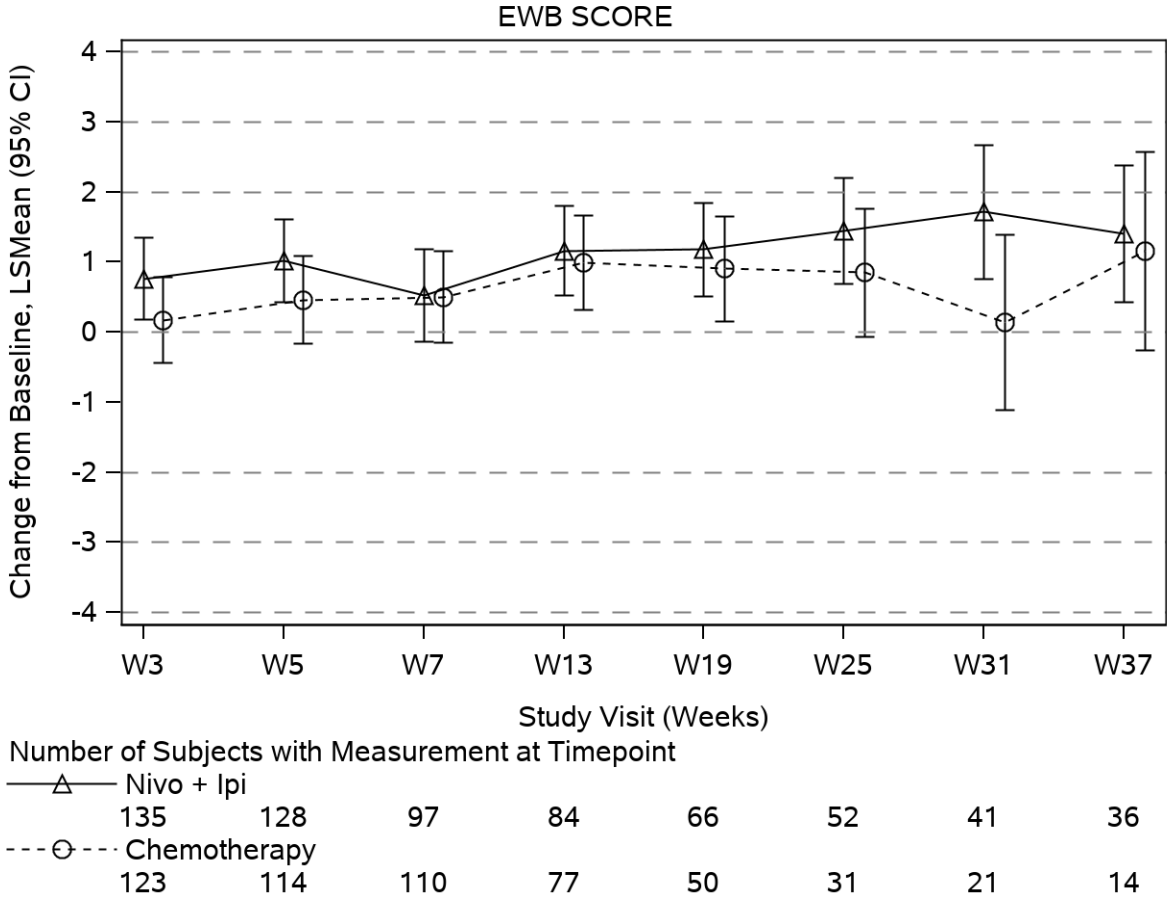
3.40 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala PWB im Behandlungsverlauf (MMRM)



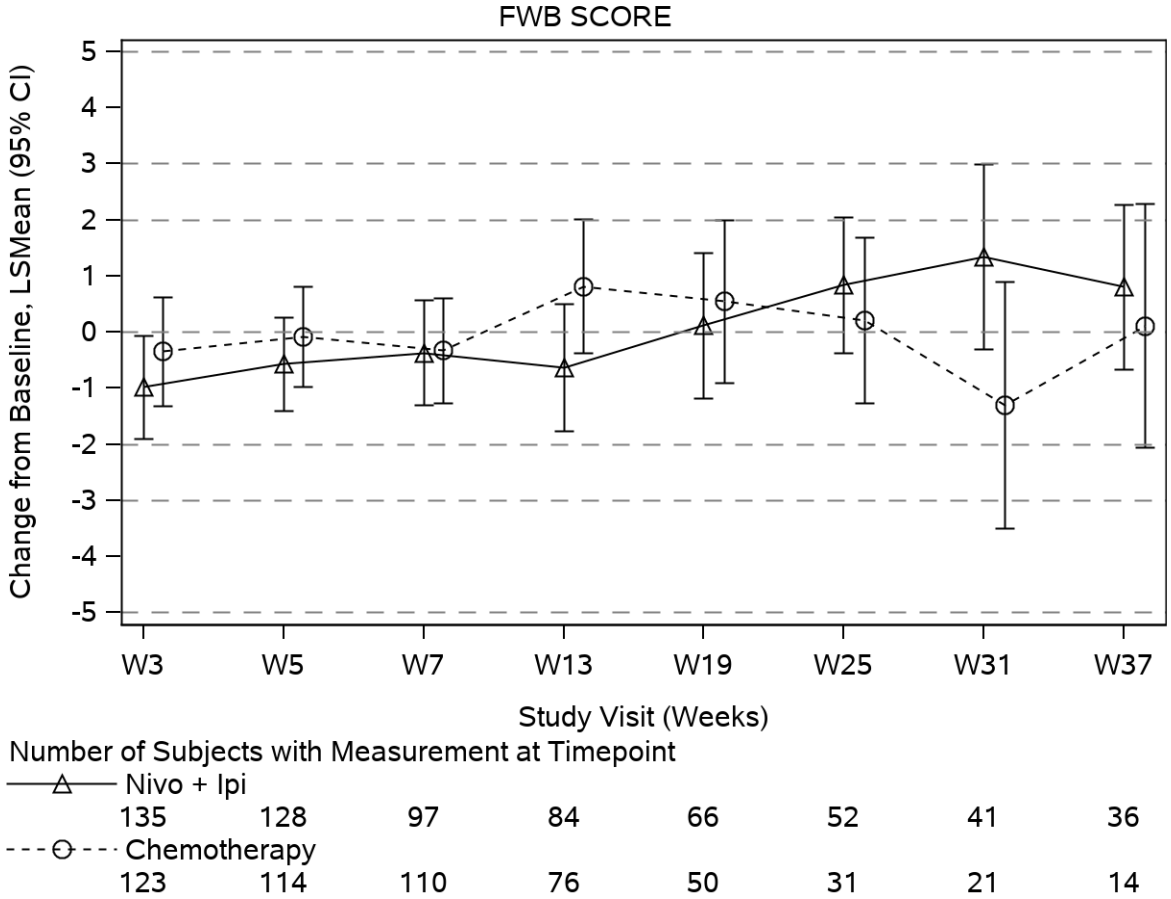
3.41 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala SWB im Behandlungsverlauf (MMRM)



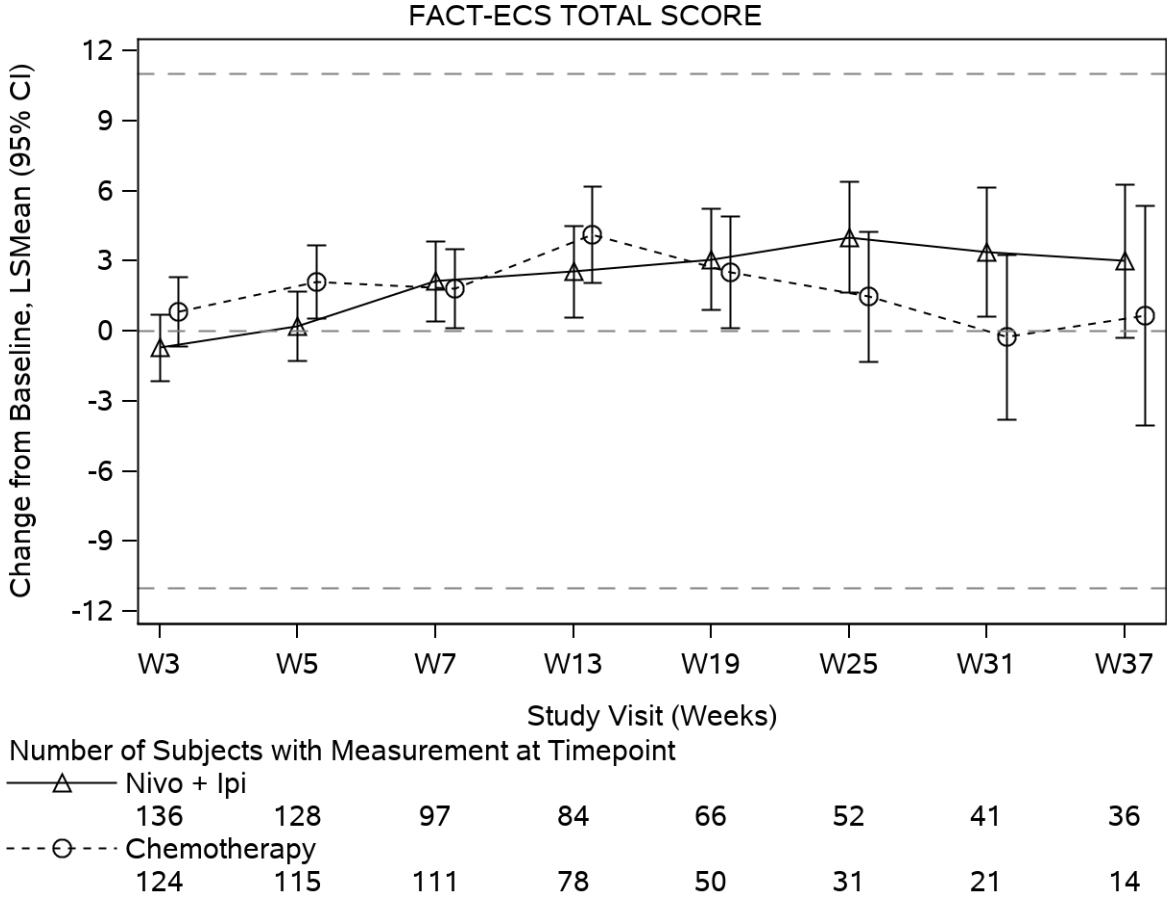
3.42 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala EWB im Behandlungsverlauf (MMRM)



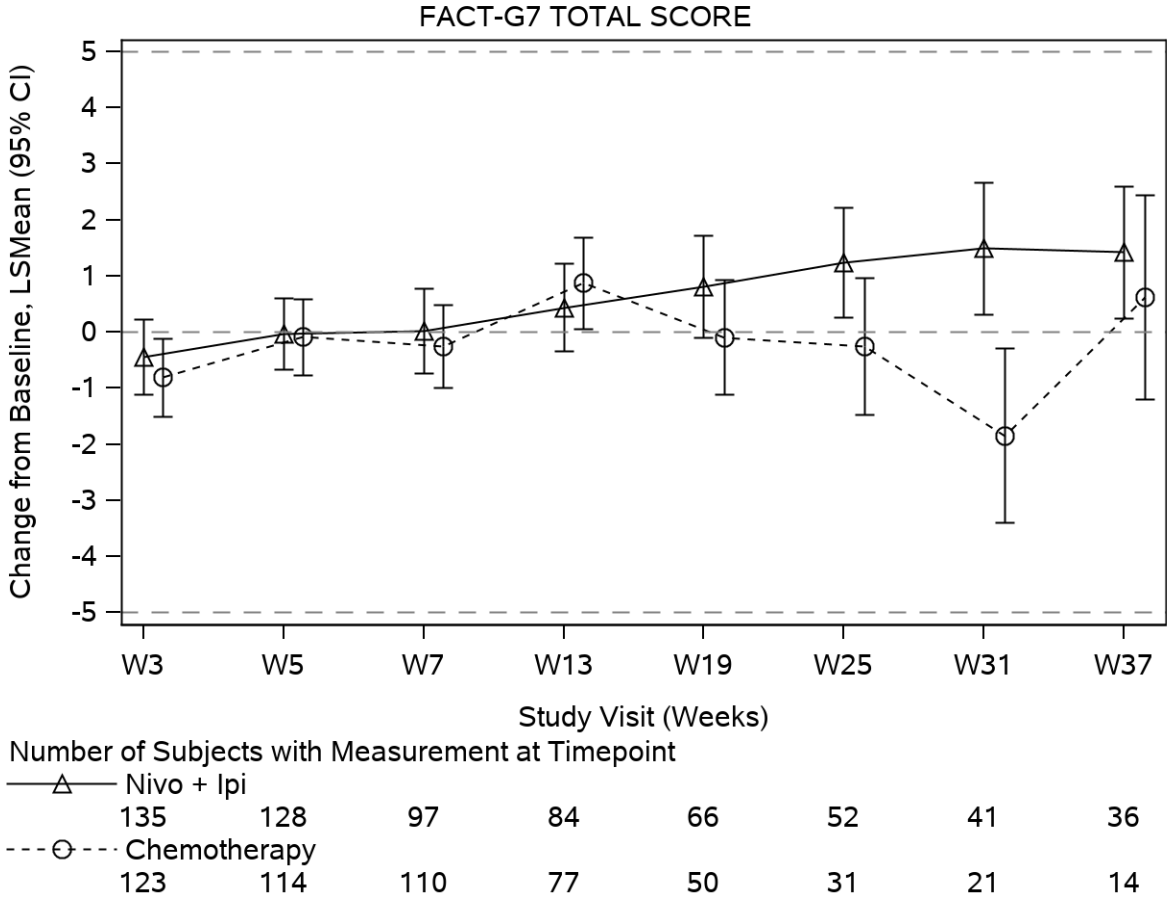
3.43 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der FACT-G Subskala FWB im Behandlungsverlauf (MMRM)



3.44 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung der ECS im Behandlungsverlauf (MMRM)



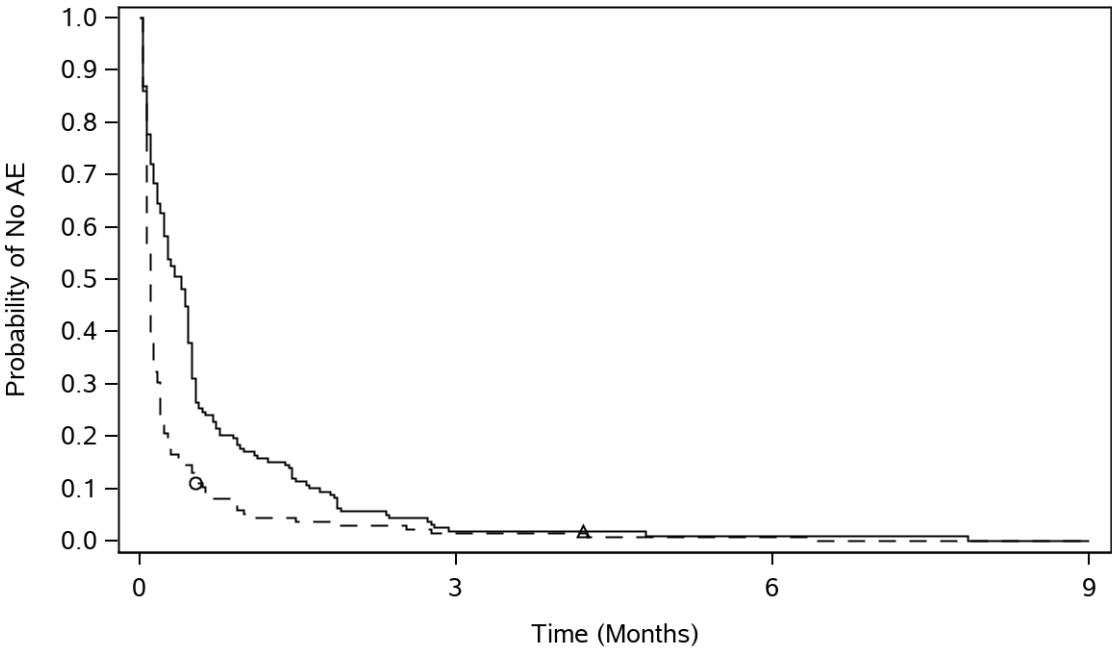
3.45 Zusatzanalyse – Graphische Darstellung der mittleren Veränderung des FACT-G7 Gesamtscores im Behandlungsverlauf (MMRM)



4 Verträglichkeit – Unerwünschte Ereignisse (Safety-Population der Patienten mit PD-L1 TC ≥ 1 %)

4.1 „Gesamtraten“ der Unerwünschten Ereignisse

4.1.1 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen UE



Number of Subjects at Risk

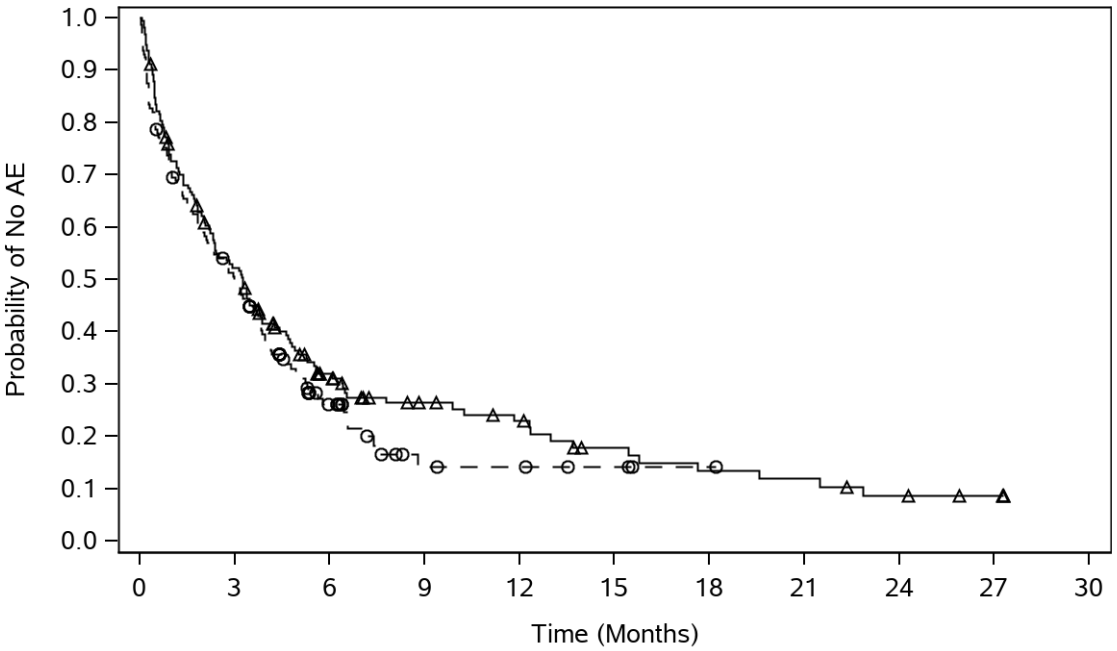
Nivo + Ipi	158	3	1	0
Chemo	145	2	1	0

Nivo + Ipi (events: 157/158), median and 95% CI: 0.39 (0.26, 0.46)

Chemo (events: 144/145), median and 95% CI: 0.10 (0.07, 0.10)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.521 (0.410, 0.662), p-value: <0.0001

4.1.2 KM-Kurven – Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3)



Number of Subjects at Risk

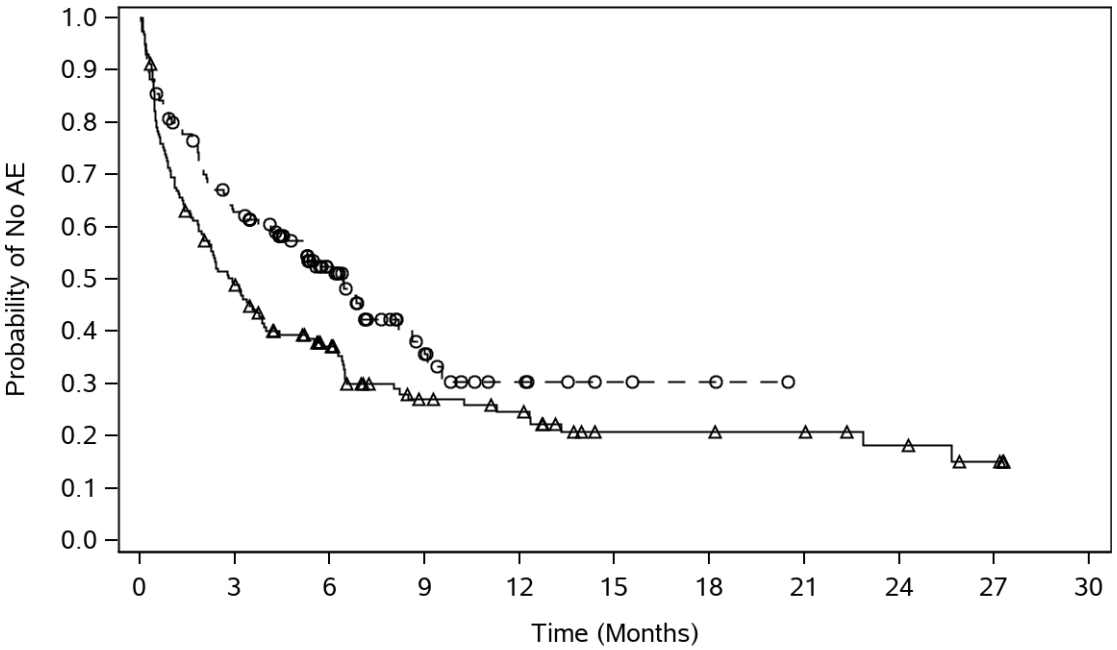
Nivo + Ipi	158	79	38	24	19	12	9	8	5	3	0
Chemo	145	70	22	6	5	3	1	0	0	0	0

—△— Nivo + Ipi (events: 122/158), median and 95% CI: 3.25 (2.30, 3.88)

—○— Chemo (events: 108/145), median and 95% CI: 2.99 (2.04, 3.75)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 0.849 (0.651, 1.107), p-value: 0.2270

4.1.3 KM-Kurven – Zeit bis zum ersten Auftreten von SUE



Number of Subjects at Risk

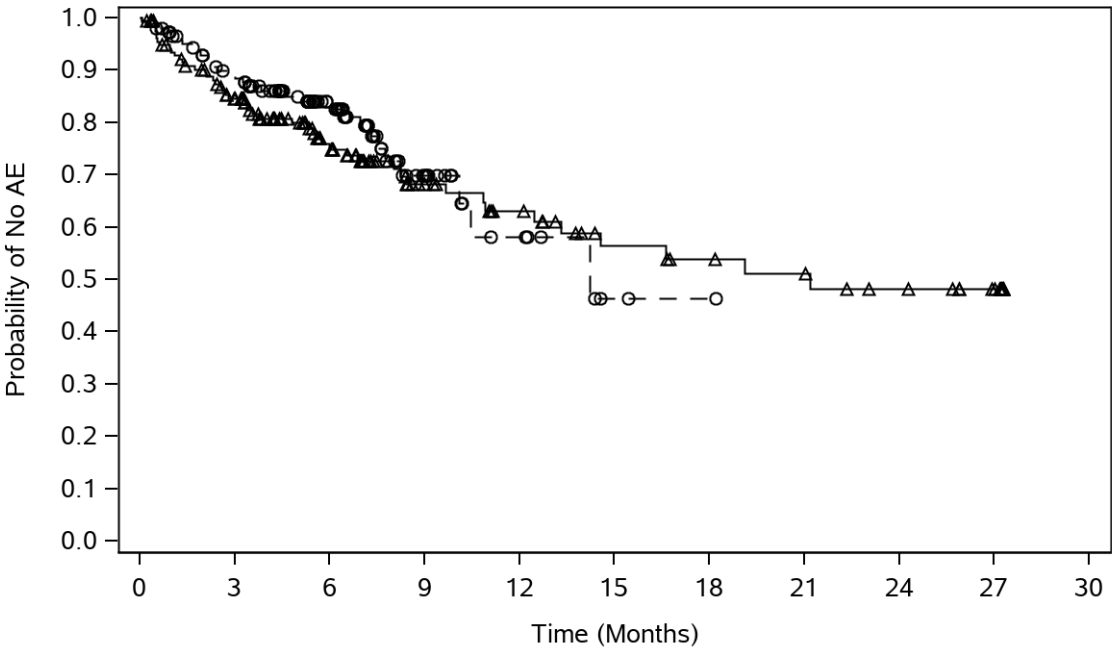
Nivo + Ipi	158	75	45	25	21	11	11	10	7	4	0
Chemo	145	87	42	17	7	3	2	0	0	0	0

—△— Nivo + Ipi (events: 115/158), median and 95% CI: 2.92 (2.00, 3.88)

—○— Chemo (events: 77/145), median and 95% CI: 6.41 (4.40, 8.18)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 1.415 (1.056, 1.896), p-value: 0.0195

4.1.4 KM-Kurven – Zeit bis zum ersten Auftreten von zum Therapieabbruch führenden UE



Number of Subjects at Risk

Nivo + Ipi	158	119	71	42	33	23	20	18	14	9	0
Chemo	145	118	61	21	8	2	1	0	0	0	0

Nivo + Ipi (events: 48/158), median and 95% CI: 21.19 (12.45, N.A.)

Chemo (events: 31/145), median and 95% CI: 14.23 (10.09, N.A.)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 1.174 (0.736, 1.873), p-value: 0.5002

4.1.5 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen UE

Protocol: CA209648 Page 1 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	157 (99.4)	0.39 (0.26, 0.46)	145	144 (99.3)	0.10 (0.07, 0.10)	0.543 (0.431, 0.685) <0.0001	
AGE								0.4212
< 65	95	95 (100.0)	0.39 (0.23, 0.46)	75	74 (98.7)	0.10 (0.07, 0.10)	0.623 (0.457, 0.849) 0.0033	
>= 65 AND < 75	55	54 (98.2)	0.33 (0.20, 0.49)	58	58 (100.0)	0.10 (0.07, 0.13)	0.458 (0.308, 0.683) <0.0001	
>= 75	8	8 (100.0)	0.59 (0.10, 1.22)	12	12 (100.0)	0.11 (0.07, 0.20)	0.290 (0.103, 0.813) 0.0154	
SEX								0.3472
MALE	131	130 (99.2)	0.33 (0.23, 0.46)	122	121 (99.2)	0.10 (0.07, 0.13)	0.572 (0.444, 0.738) <0.0001	
FEMALE	27	27 (100.0)	0.49 (0.23, 0.53)	23	23 (100.0)	0.10 (0.07, 0.10)	0.398 (0.219, 0.722) 0.0023	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 2 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.8001
ASIAN	117	117 (100.0)	0.30 (0.23, 0.46)	104	103 (99.0)	0.10 (0.07, 0.10)	0.569 (0.433, 0.749) <0.0001	
NON-ASIAN	41	40 (97.6)	0.43 (0.26, 0.49)	41	41 (100.0)	0.10 (0.07, 0.20)	0.491 (0.314, 0.770) 0.0016	
REGION (PER CRF)								0.4604
J/K/T	91	91 (100.0)	0.39 (0.23, 0.49)	85	84 (98.8)	0.10 (0.07, 0.10)	0.538 (0.394, 0.735) 0.0002	
REST OF ASIA	25	25 (100.0)	0.23 (0.13, 0.46)	19	19 (100.0)	0.10 (0.03, 0.23)	0.782 (0.425, 1.437) 0.4235	
REST OF WORLD	42	41 (97.6)	0.44 (0.26, 0.46)	41	41 (100.0)	0.10 (0.07, 0.20)	0.491 (0.314, 0.768) 0.0014	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 3 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8097
ASIA	116	116 (100.0)	0.28 (0.16, 0.46)	104	103 (99.0)	0.10 (0.07, 0.10)	0.571 (0.434, 0.751) 0.0001	
NON-ASIA	42	41 (97.6)	0.44 (0.26, 0.46)	41	41 (100.0)	0.10 (0.07, 0.20)	0.491 (0.314, 0.768) 0.0014	
ECOG PS (PER CRF)								0.0958
0	71	71 (100.0)	0.46 (0.26, 0.49)	69	68 (98.6)	0.07 (0.07, 0.10)	0.457 (0.322, 0.647) <0.0001	
1	87	86 (98.9)	0.26 (0.20, 0.43)	74	74 (100.0)	0.10 (0.10, 0.16)	0.641 (0.467, 0.880) 0.0055	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 4 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
WEIGHT								0.2944
< 60 KG	96	96 (100.0)	0.33 (0.23, 0.46)	76	75 (98.7)	0.10 (0.07, 0.13)	0.614 (0.451, 0.838) 0.0026	
>= 60 KG	62	61 (98.4)	0.43 (0.20, 0.49)	69	69 (100.0)	0.10 (0.07, 0.13)	0.464 (0.323, 0.665) <0.0001	
DISEASE STAGE AT INITIAL DIAGNOSIS								0.1510
STAGE I	5	5 (100.0)	0.49 (0.03, N.A.)	5	5 (100.0)	0.10 (0.07, N.A.)	0.127 (0.014, 1.147) 0.0350	
STAGE II	5	5 (100.0)	0.43 (0.10, N.A.)	5	5 (100.0)	0.10 (0.03, N.A.)	0.294 (0.067, 1.298) 0.1058	
STAGE III	33	33 (100.0)	0.49 (0.39, 0.99)	46	46 (100.0)	0.08 (0.07, 0.13)	0.379 (0.236, 0.607) <0.0001	
STAGE IV	114	113 (99.1)	0.26 (0.16, 0.43)	89	88 (98.9)	0.10 (0.07, 0.13)	0.655 (0.494, 0.870) 0.0042	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 5 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.3066
GX	11	11 (100.0)	0.26 (0.07, 1.71)	14	14 (100.0)	0.10 (0.07, 0.13)	0.283 (0.107, 0.750) 0.0100	
G1	8	8 (100.0)	0.43 (0.03, 0.72)	8	8 (100.0)	0.08 (0.03, 0.13)	0.243 (0.062, 0.962) 0.0284	
G2	58	57 (98.3)	0.26 (0.16, 0.46)	50	50 (100.0)	0.10 (0.07, 0.10)	0.598 (0.406, 0.882) 0.0112	
G3	28	28 (100.0)	0.46 (0.10, 0.53)	36	35 (97.2)	0.13 (0.07, 0.20)	0.723 (0.434, 1.202) 0.2009	
NOT OTHERWISE SPECIFIED	51	51 (100.0)	0.43 (0.26, 0.49)	37	37 (100.0)	0.10 (0.07, 0.20)	0.380 (0.239, 0.602) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 6 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.1890
UPPER THORACIC	37	37 (100.0)	0.43 (0.23, 0.53)	25	25 (100.0)	0.07 (0.07, 0.10)	0.301 (0.171, 0.532) <0.0001	
MIDDLE THORACIC	50	49 (98.0)	0.46 (0.26, 0.49)	52	52 (100.0)	0.11 (0.07, 0.20)	0.659 (0.443, 0.981) 0.0437	
LOWER THORACIC	59	59 (100.0)	0.23 (0.10, 0.39)	60	60 (100.0)	0.10 (0.07, 0.10)	0.466 (0.315, 0.689) 0.0001	
GASTROESOPHAGEAL JUNCTION	11	11 (100.0)	0.46 (0.10, 1.45)	8	7 (87.5)	0.21 (0.03, N.A.)	0.630 (0.227, 1.751) 0.3527	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 7 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.0011*
RECURRENT - LOCO-REGIONAL	8	8 (100.0)	0.99 (0.23, 1.87)	13	13 (100.0)	0.10 (0.07, 0.10)	0.132 (0.040, 0.435) 0.0004	
RECURRENT - DISTANT	25	25 (100.0)	0.49 (0.23, 1.22)	27	27 (100.0)	0.07 (0.07, 0.13)	0.226 (0.114, 0.445) <0.0001	
DE NOVO METASTATIC	107	106 (99.1)	0.26 (0.16, 0.43)	81	80 (98.8)	0.10 (0.07, 0.13)	0.627 (0.466, 0.843) 0.0023	
UNRESECTABLE ADVANCED	18	18 (100.0)	0.41 (0.10, 0.49)	24	24 (100.0)	0.11 (0.07, 0.20)	0.798 (0.420, 1.515) 0.5439	
SMOKING STATUS								0.6304
CURRENT/FORMER	136	135 (99.3)	0.39 (0.23, 0.46)	111	110 (99.1)	0.10 (0.07, 0.10)	0.544 (0.420, 0.705) <0.0001	
NEVER/UNKNOWN	22	22 (100.0)	0.26 (0.13, 0.53)	34	34 (100.0)	0.10 (0.07, 0.16)	0.499 (0.283, 0.880) 0.0157	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 8 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.1540
CURRENT/FORMER	126	125 (99.2)	0.41 (0.26, 0.46)	117	116 (99.1)	0.10 (0.07, 0.10)	0.482 (0.371, 0.626) <0.0001	
NEVER/UNKNOWN	32	32 (100.0)	0.25 (0.10, 0.49)	28	28 (100.0)	0.10 (0.07, 0.20)	0.794 (0.474, 1.330) 0.4237	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.0163*
<= 1	80	80 (100.0)	0.31 (0.16, 0.46)	69	69 (100.0)	0.10 (0.10, 0.20)	0.701 (0.505, 0.973) 0.0358	
>= 2	78	77 (98.7)	0.43 (0.26, 0.49)	76	75 (98.7)	0.07 (0.07, 0.10)	0.382 (0.272, 0.536) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 9 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.0119*
< 1 YEAR	128	127 (99.2)	0.26 (0.20, 0.39)	115	114 (99.1)	0.10 (0.07, 0.13)	0.659 (0.510, 0.852) 0.0020	
1 - < 3 YEARS	25	25 (100.0)	0.49 (0.43, 1.45)	21	21 (100.0)	0.10 (0.07, 0.10)	0.216 (0.107, 0.437) <0.0001	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0026*
YES	38	38 (100.0)	0.44 (0.20, 0.53)	37	37 (100.0)	0.07 (0.07, 0.10)	0.273 (0.159, 0.470) <0.0001	
NO	120	119 (99.2)	0.33 (0.23, 0.46)	108	107 (99.1)	0.10 (0.07, 0.13)	0.635 (0.487, 0.829) 0.0012	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 10 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.0016*
YES	26	26 (100.0)	0.48 (0.43, 1.38)	27	27 (100.0)	0.07 (0.07, 0.10)	0.199 (0.104, 0.381) <0.0001	
NO	132	131 (99.2)	0.26 (0.20, 0.43)	118	117 (99.2)	0.10 (0.10, 0.13)	0.645 (0.500, 0.831) 0.0009	
PD-L1 CPS I								0.6371
< 10	53	52 (98.1)	0.43 (0.20, 0.53)	54	54 (100.0)	0.10 (0.07, 0.13)	0.494 (0.333, 0.734) 0.0004	
>= 10	92	92 (100.0)	0.39 (0.23, 0.46)	89	88 (98.9)	0.10 (0.07, 0.10)	0.553 (0.408, 0.749) 0.0002	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 11 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.4866
< 5	29	29 (100.0)	0.26 (0.16, 0.49)	24	24 (100.0)	0.08 (0.07, 0.16)	0.399 (0.223, 0.714) 0.0015	
>= 5	116	115 (99.1)	0.43 (0.26, 0.46)	119	118 (99.2)	0.10 (0.07, 0.10)	0.564 (0.433, 0.735) <0.0001	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.2015
< 10%	55	54 (98.2)	0.43 (0.16, 0.53)	57	57 (100.0)	0.10 (0.07, 0.13)	0.422 (0.280, 0.634) <0.0001	
>= 10%	103	103 (100.0)	0.39 (0.23, 0.46)	88	87 (98.9)	0.10 (0.07, 0.10)	0.592 (0.442, 0.792) 0.0006	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

Protocol: CA209648 Page 12 of 12

Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2406
< 5%	38	37 (97.4)	0.38 (0.16, 0.53)	41	41 (100.0)	0.07 (0.07, 0.13)	0.415 (0.253, 0.678) 0.0003	
>= 5%	120	120 (100.0)	0.39 (0.23, 0.46)	104	103 (99.0)	0.10 (0.07, 0.10)	0.578 (0.442, 0.757) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:42

4.1.6 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3)

Protocol: CA209648 Page 1 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	122 (77.2)	3.25 (2.30, 3.88)	145	108 (74.5)	2.99 (2.04, 3.75)	0.864 (0.664, 1.125) 0.2774	
AGE								0.2459
< 65	95	73 (76.8)	3.25 (2.23, 4.73)	75	55 (73.3)	2.99 (1.87, 3.94)	0.932 (0.655, 1.326) 0.6951	
>= 65 AND < 75	55	42 (76.4)	2.50 (1.84, 4.27)	58	42 (72.4)	3.42 (2.10, 4.14)	0.900 (0.578, 1.402) 0.6368	
>= 75	8	7 (87.5)	3.63 (0.13, 21.49)	12	11 (91.7)	1.02 (0.23, 3.02)	0.468 (0.169, 1.297) 0.1344	
SEX								0.6679
MALE	131	100 (76.3)	3.25 (2.23, 4.27)	122	91 (74.6)	3.15 (2.27, 3.88)	0.878 (0.658, 1.172) 0.3765	
FEMALE	27	22 (81.5)	2.50 (0.99, 5.03)	23	17 (73.9)	1.28 (0.26, 4.60)	0.783 (0.412, 1.487) 0.4589	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 2 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.4437
ASIAN	117	91 (77.8)	3.25 (2.23, 3.88)	104	76 (73.1)	3.19 (2.27, 3.88)	0.922 (0.676, 1.256) 0.6082	
NON-ASIAN	41	31 (75.6)	3.81 (1.38, 6.37)	41	32 (78.0)	2.10 (1.02, 4.47)	0.718 (0.430, 1.200) 0.2025	
REGION (PER CRF)								0.4155
J/K/T	91	71 (78.0)	3.12 (1.84, 3.88)	85	61 (71.8)	3.32 (2.30, 3.94)	0.986 (0.696, 1.397) 0.9411	
REST OF ASIA	25	19 (76.0)	3.48 (2.23, 6.54)	19	15 (78.9)	2.27 (0.49, 3.94)	0.594 (0.294, 1.197) 0.1405	
REST OF WORLD	42	32 (76.2)	2.83 (1.22, 6.37)	41	32 (78.0)	2.10 (1.02, 4.47)	0.741 (0.446, 1.231) 0.2411	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 3 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5174
ASIA	116	90 (77.6)	3.25 (2.30, 3.88)	104	76 (73.1)	3.19 (2.27, 3.88)	0.912 (0.669, 1.244) 0.5651	
NON-ASIA	42	32 (76.2)	2.83 (1.22, 6.37)	41	32 (78.0)	2.10 (1.02, 4.47)	0.741 (0.446, 1.231) 0.2411	
ECOG PS (PER CRF)								0.3801
0	71	54 (76.1)	3.25 (2.37, 4.80)	69	52 (75.4)	3.02 (1.38, 3.75)	0.754 (0.511, 1.110) 0.1532	
1	87	68 (78.2)	2.83 (1.58, 4.27)	74	54 (73.0)	2.96 (1.87, 4.47)	0.975 (0.676, 1.407) 0.8906	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 4 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
WEIGHT								0.9232
< 60 KG	96	78 (81.3)	2.83 (2.04, 3.81)	76	57 (75.0)	2.10 (1.35, 3.68)	0.844 (0.597, 1.194) 0.3389	
>= 60 KG	62	44 (71.0)	3.48 (1.84, 5.29)	69	51 (73.9)	3.58 (2.46, 4.47)	0.840 (0.556, 1.268) 0.4054	
DISEASE STAGE AT INITIAL DIAGNOSIS								0.2537
STAGE I	5	4 (80.0)	9.28 (4.73, N.A.)	5	5 (100.0)	3.15 (0.20, N.A.)	0.192 (0.036, 1.024) 0.0333	
STAGE II	5	5 (100.0)	2.30 (0.13, N.A.)	5	4 (80.0)	0.10 (0.03, N.A.)	0.926 (0.240, 3.567) 0.9472	
STAGE III	33	22 (66.7)	4.40 (2.30, 12.32)	46	34 (73.9)	2.05 (0.92, 4.14)	0.629 (0.366, 1.082) 0.0906	
STAGE IV	114	90 (78.9)	2.50 (1.81, 3.48)	89	65 (73.0)	3.32 (2.14, 3.94)	1.033 (0.747, 1.429) 0.8405	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 5 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.3458
GX	11	9 (81.8)	0.89 (0.23, N.A.)	14	10 (71.4)	3.81 (0.76, N.A.)	2.247 (0.861, 5.867) 0.0908	
G1	8	7 (87.5)	4.30 (0.26, 12.98)	8	6 (75.0)	4.16 (1.64, N.A.)	0.938 (0.295, 2.986) 0.9136	
G2	58	44 (75.9)	3.38 (1.64, 4.70)	50	41 (82.0)	2.20 (0.95, 3.88)	0.739 (0.480, 1.137) 0.1677	
G3	28	19 (67.9)	5.26 (1.25, 15.77)	36	24 (66.7)	2.79 (1.84, 4.17)	0.748 (0.396, 1.415) 0.3651	
NOT OTHERWISE SPECIFIED	51	41 (80.4)	2.50 (1.94, 3.75)	37	27 (73.0)	3.02 (1.35, 4.60)	0.923 (0.562, 1.515) 0.7553	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 6 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.0562
UPPER THORACIC	37	31 (83.8)	3.75 (2.04, 5.59)	25	19 (76.0)	3.25 (1.35, 5.32)	0.912 (0.512, 1.626) 0.7557	
MIDDLE THORACIC	50	37 (74.0)	2.30 (1.38, 3.48)	52	37 (71.2)	3.19 (1.87, 4.76)	1.169 (0.738, 1.853) 0.5063	
LOWER THORACIC	59	44 (74.6)	3.48 (1.84, 5.29)	60	49 (81.7)	2.14 (1.02, 3.32)	0.599 (0.392, 0.916) 0.0172	
GASTROESOPHAGEAL JUNCTION	11	9 (81.8)	2.33 (0.46, N.A.)	8	3 (37.5)	N.A. (0.16, N.A.)	1.966 (0.506, 7.645) 0.3246	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 7 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.0928
RECURRENT - LOCO-REGIONAL	8	6 (75.0)	7.34 (0.46, N.A.)	13	13 (100.0)	1.35 (0.26, 3.15)	0.299 (0.095, 0.943) 0.0269	
RECURRENT - DISTANT	25	17 (68.0)	4.73 (2.00, 10.25)	27	20 (74.1)	1.64 (0.26, 4.17)	0.535 (0.270, 1.059) 0.0678	
DE NOVO METASTATIC	107	86 (80.4)	2.73 (1.84, 3.48)	81	61 (75.3)	3.25 (1.87, 3.84)	0.986 (0.706, 1.378) 0.9408	
UNRESECTABLE ADVANCED	18	13 (72.2)	4.40 (1.64, 12.32)	24	14 (58.3)	4.14 (2.27, N.A.)	1.174 (0.551, 2.502) 0.6779	
SMOKING STATUS								0.3884
CURRENT/FORMER	136	106 (77.9)	3.22 (2.23, 3.81)	111	81 (73.0)	3.19 (2.30, 3.88)	0.913 (0.679, 1.227) 0.5414	
NEVER/UNKNOWN	22	16 (72.7)	3.88 (0.99, 6.47)	34	27 (79.4)	1.84 (0.49, 4.14)	0.690 (0.370, 1.286) 0.2442	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 8 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.5189
CURRENT/FORMER	126	99 (78.6)	3.19 (2.20, 3.78)	117	90 (76.9)	2.73 (1.84, 3.58)	0.840 (0.628, 1.123) 0.2383	
NEVER/UNKNOWN	32	23 (71.9)	5.26 (1.22, 7.79)	28	18 (64.3)	4.60 (1.48, 7.39)	0.949 (0.506, 1.782) 0.8709	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.6482
<= 1	80	65 (81.3)	3.38 (2.20, 4.70)	69	54 (78.3)	3.19 (2.30, 3.94)	0.901 (0.623, 1.303) 0.5791	
>= 2	78	57 (73.1)	2.73 (1.81, 4.63)	76	54 (71.1)	2.27 (1.15, 3.94)	0.814 (0.558, 1.189) 0.2870	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 9 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3006
< 1 YEAR	128	101 (78.9)	3.22 (2.04, 3.88)	115	84 (73.0)	3.12 (2.04, 3.84)	0.958 (0.714, 1.285) 0.7755	
1 - < 3 YEARS	25	17 (68.0)	3.25 (1.38, 10.25)	21	17 (81.0)	2.33 (0.30, 5.62)	0.617 (0.307, 1.239) 0.1685	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0394*
YES	38	27 (71.1)	3.53 (2.30, 6.54)	37	29 (78.4)	2.30 (0.59, 4.04)	0.524 (0.302, 0.907) 0.0183	
NO	120	95 (79.2)	3.22 (1.84, 3.88)	108	79 (73.1)	3.19 (2.14, 3.88)	1.010 (0.746, 1.367) 0.9491	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 10 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1977
YES	26	19 (73.1)	3.19 (1.38, 10.25)	27	21 (77.8)	1.02 (0.30, 3.94)	0.559 (0.288, 1.084) 0.0798	
NO	132	103 (78.0)	3.25 (2.20, 4.27)	118	87 (73.7)	3.15 (2.14, 3.84)	0.935 (0.700, 1.249) 0.6505	
PD-L1 CPS I								0.5163
< 10	53	38 (71.7)	3.38 (1.64, 5.55)	54	39 (72.2)	1.87 (1.28, 3.02)	0.784 (0.498, 1.233) 0.2918	
>= 10	92	72 (78.3)	3.22 (2.23, 3.88)	89	67 (75.3)	3.42 (2.33, 4.14)	0.910 (0.648, 1.279) 0.5885	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 11 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.5095
< 5	29	20 (69.0)	1.64 (0.49, 6.54)	24	18 (75.0)	1.48 (0.49, 2.79)	0.791 (0.414, 1.512) 0.4793	
>= 5	116	90 (77.6)	3.38 (2.37, 4.40)	119	88 (73.9)	3.25 (2.27, 3.94)	0.882 (0.654, 1.188) 0.4086	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.1456
< 10%	55	38 (69.1)	4.27 (2.30, 6.47)	57	44 (77.2)	2.10 (1.48, 4.47)	0.660 (0.424, 1.028) 0.0646	
>= 10%	103	84 (81.6)	2.73 (1.84, 3.38)	88	64 (72.7)	3.25 (2.33, 3.84)	1.023 (0.734, 1.424) 0.8914	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:32:55

Protocol: CA209648 Page 12 of 12

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2373
< 5%	38	25 (65.8)	4.40 (2.20, 6.54)	41	32 (78.0)	2.73 (1.31, 4.60)	0.664 (0.390, 1.130) 0.1286	
>= 5%	120	97 (80.8)	2.92 (1.94, 3.48)	104	76 (73.1)	3.15 (2.10, 3.81)	0.960 (0.707, 1.304) 0.7964	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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4.1.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von SUE

Protocol: CA209648 Page 1 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	115 (72.8)	2.92 (2.00, 3.88)	145	77 (53.1)	6.41 (4.40, 8.18)	1.455 (1.088, 1.947) 0.0110	
AGE								0.0998
< 65	95	66 (69.5)	3.25 (2.20, 6.18)	75	44 (58.7)	5.32 (2.37, 8.61)	1.229 (0.837, 1.804) 0.2923	
>= 65 AND < 75	55	43 (78.2)	2.00 (1.08, 3.78)	58	25 (43.1)	6.57 (4.40, N.A.)	2.208 (1.341, 3.636) 0.0014	
>= 75	8	6 (75.0)	3.32 (0.13, N.A.)	12	8 (66.7)	2.04 (0.20, N.A.)	0.756 (0.246, 2.328) 0.6254	
SEX								0.4442
MALE	131	92 (70.2)	3.12 (2.20, 3.91)	122	66 (54.1)	6.41 (4.40, 8.18)	1.380 (1.003, 1.897) 0.0471	
FEMALE	27	23 (85.2)	1.38 (0.56, 6.37)	23	11 (47.8)	N.A. (0.72, N.A.)	1.850 (0.896, 3.821) 0.0906	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 2 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.6488
ASIAN	117	86 (73.5)	2.92 (1.94, 3.88)	104	54 (51.9)	6.11 (3.75, 9.00)	1.522 (1.080, 2.145) 0.0155	
NON-ASIAN	41	29 (70.7)	2.79 (1.38, 6.44)	41	23 (56.1)	6.83 (2.69, 9.10)	1.280 (0.735, 2.230) 0.3810	
REGION (PER CRF)								0.1694
J/K/T	91	70 (76.9)	2.40 (1.35, 3.88)	85	43 (50.6)	6.41 (4.40, 9.00)	1.764 (1.202, 2.589) 0.0033	
REST OF ASIA	25	15 (60.0)	3.71 (1.41, N.A.)	19	11 (57.9)	1.87 (0.62, N.A.)	0.847 (0.387, 1.852) 0.6826	
REST OF WORLD	42	30 (71.4)	2.79 (1.41, 6.44)	41	23 (56.1)	6.83 (2.69, 9.10)	1.285 (0.741, 2.228) 0.3692	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 3 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.6511
ASIA	116	85 (73.3)	2.92 (1.87, 3.88)	104	54 (51.9)	6.11 (3.75, 9.00)	1.525 (1.082, 2.152) 0.0153	
NON-ASIA	42	30 (71.4)	2.79 (1.41, 6.44)	41	23 (56.1)	6.83 (2.69, 9.10)	1.285 (0.741, 2.228) 0.3692	
ECOG PS (PER CRF)								0.9956
0	71	51 (71.8)	3.15 (2.20, 5.75)	69	35 (50.7)	7.00 (2.92, N.A.)	1.494 (0.970, 2.303) 0.0667	
1	87	64 (73.6)	2.33 (1.15, 5.29)	74	40 (54.1)	6.41 (4.17, 9.10)	1.453 (0.973, 2.170) 0.0656	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 4 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
WEIGHT								0.2896
< 60 KG	96	77 (80.2)	2.30 (1.58, 3.19)	76	41 (53.9)	6.41 (2.37, 9.10)	1.597 (1.090, 2.338) 0.0151	
>= 60 KG	62	38 (61.3)	3.88 (2.00, 12.35)	69	36 (52.2)	6.44 (4.67, 8.61)	1.209 (0.762, 1.919) 0.4195	
DISEASE STAGE AT INITIAL DIAGNOSIS								0.6452
STAGE I	5	3 (60.0)	11.27 (0.03, N.A.)	5	2 (40.0)	9.56 (0.20, N.A.)	1.382 (0.227, 8.428) 0.7247	
STAGE II	5	4 (80.0)	2.30 (0.13, N.A.)	5	2 (40.0)	N.A. (0.10, N.A.)	1.828 (0.330, 10.142) 0.4473	
STAGE III	33	22 (66.7)	5.52 (1.94, 12.32)	46	25 (54.3)	4.67 (2.37, N.A.)	1.072 (0.601, 1.910) 0.8201	
STAGE IV	114	86 (75.4)	2.40 (1.41, 3.55)	89	48 (53.9)	6.41 (3.75, 8.18)	1.597 (1.118, 2.280) 0.0094	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 5 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.4836
GX	11	10 (90.9)	0.89 (0.26, 6.37)	14	6 (42.9)	7.00 (2.37, N.A.)	3.209 (1.130, 9.112) 0.0210	
G1	8	5 (62.5)	4.67 (0.43, N.A.)	8	3 (37.5)	N.A. (0.10, N.A.)	1.705 (0.404, 7.183) 0.4623	
G2	58	43 (74.1)	2.35 (1.15, 4.40)	50	29 (58.0)	6.41 (2.83, 9.00)	1.347 (0.837, 2.167) 0.2172	
G3	28	16 (57.1)	6.28 (1.84, N.A.)	36	15 (41.7)	N.A. (4.17, N.A.)	1.325 (0.651, 2.694) 0.4343	
NOT OTHERWISE SPECIFIED	51	39 (76.5)	2.46 (1.22, 3.91)	37	24 (64.9)	3.29 (1.91, 6.57)	1.128 (0.672, 1.894) 0.6530	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 6 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.0286*
UPPER THORACIC	37	29 (78.4)	3.78 (1.61, 6.18)	25	15 (60.0)	5.32 (1.35, 7.00)	1.166 (0.621, 2.189) 0.6317	
MIDDLE THORACIC	50	38 (76.0)	2.20 (1.08, 2.76)	52	25 (48.1)	9.00 (4.67, 9.56)	2.129 (1.279, 3.543) 0.0030	
LOWER THORACIC	59	37 (62.7)	5.29 (1.87, 8.48)	60	35 (58.3)	5.22 (2.66, 6.83)	0.976 (0.611, 1.561) 0.9181	
GASTROESOPHAGEAL JUNCTION	11	10 (90.9)	1.22 (0.16, 11.27)	8	2 (25.0)	8.18 (4.14, N.A.)	3.863 (0.808, 18.465) 0.0694	

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(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 7 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5757
RECURRENT - LOCO-REGIONAL	8	6 (75.0)	6.80 (0.46, N.A.)	13	5 (38.5)	N.A. (0.30, N.A.)	1.763 (0.535, 5.807) 0.3511	
RECURRENT - DISTANT	25	16 (64.0)	2.92 (1.41, N.A.)	27	13 (48.1)	7.00 (0.72, N.A.)	1.123 (0.532, 2.371) 0.7573	
DE NOVO METASTATIC	107	82 (76.6)	2.37 (1.35, 3.38)	81	45 (55.6)	6.41 (3.29, 6.97)	1.619 (1.122, 2.337) 0.0094	
UNRESECTABLE ADVANCED	18	11 (61.1)	6.47 (3.91, 12.32)	24	14 (58.3)	4.67 (2.76, N.A.)	0.881 (0.398, 1.949) 0.7537	
SMOKING STATUS								0.4054
CURRENT/FORMER	136	100 (73.5)	2.79 (1.87, 3.78)	111	58 (52.3)	6.44 (4.17, 9.00)	1.536 (1.109, 2.129) 0.0093	
NEVER/UNKNOWN	22	15 (68.2)	3.88 (0.99, 25.66)	34	19 (55.9)	5.22 (0.92, N.A.)	1.108 (0.554, 2.215) 0.7616	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 8 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.8192
CURRENT/FORMER	126	95 (75.4)	2.61 (1.87, 3.78)	117	64 (54.7)	6.41 (3.75, 8.61)	1.497 (1.088, 2.060) 0.0125	
NEVER/UNKNOWN	32	20 (62.5)	6.37 (1.22, 12.32)	28	13 (46.4)	6.97 (1.97, N.A.)	1.309 (0.643, 2.668) 0.4547	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.6326
<= 1	80	60 (75.0)	2.99 (1.84, 3.91)	69	39 (56.5)	6.11 (2.92, 9.56)	1.561 (1.040, 2.344) 0.0300	
>= 2	78	55 (70.5)	2.79 (1.58, 6.37)	76	38 (50.0)	6.44 (4.40, 8.18)	1.303 (0.855, 1.985) 0.2160	

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(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 9 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.5001
< 1 YEAR	128	96 (75.0)	2.76 (1.84, 3.78)	115	64 (55.7)	5.52 (3.75, 6.97)	1.478 (1.074, 2.035) 0.0159	
1 - < 3 YEARS	25	16 (64.0)	3.19 (1.38, 12.35)	21	8 (38.1)	9.56 (4.17, N.A.)	1.729 (0.733, 4.075) 0.2076	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9623
YES	38	25 (65.8)	3.06 (2.00, 8.02)	37	16 (43.2)	9.56 (1.35, N.A.)	1.447 (0.771, 2.715) 0.2459	
NO	120	90 (75.0)	2.79 (1.61, 3.88)	108	61 (56.5)	5.52 (3.38, 6.97)	1.460 (1.050, 2.028) 0.0236	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 10 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2880
YES	26	19 (73.1)	2.61 (0.49, 10.25)	27	10 (37.0)	N.A. (0.72, N.A.)	1.850 (0.853, 4.011) 0.1127	
NO	132	96 (72.7)	2.99 (2.00, 3.88)	118	67 (56.8)	5.52 (3.75, 6.97)	1.382 (1.009, 1.893) 0.0430	
PD-L1 CPS I								0.8629
< 10	53	37 (69.8)	2.92 (1.61, 6.54)	54	27 (50.0)	6.44 (2.96, N.A.)	1.490 (0.906, 2.451) 0.1123	
>= 10	92	69 (75.0)	2.46 (1.38, 3.55)	89	49 (55.1)	6.11 (3.75, 9.10)	1.451 (1.001, 2.104) 0.0479	

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(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

Protocol: CA209648 Page 11 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.4806
< 5	29	20 (69.0)	1.87 (0.49, 6.54)	24	11 (45.8)	4.67 (1.84, N.A.)	1.845 (0.882, 3.859) 0.0994	
>= 5	116	86 (74.1)	2.99 (2.00, 3.88)	119	65 (54.6)	6.41 (4.14, 8.18)	1.386 (1.000, 1.920) 0.0490	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.4867
< 10%	55	39 (70.9)	3.55 (1.61, 6.47)	57	31 (54.4)	6.57 (2.10, 8.18)	1.263 (0.786, 2.030) 0.3307	
>= 10%	103	76 (73.8)	2.46 (1.84, 3.88)	88	46 (52.3)	6.41 (4.14, 9.56)	1.573 (1.086, 2.279) 0.0155	

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(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Protocol: CA209648 Page 12 of 12

Serious Adverse Events: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.8908
< 5%	38	26 (68.4)	3.78 (1.61, 6.54)	41	20 (48.8)	7.00 (3.38, N.A.)	1.531 (0.854, 2.745) 0.1479	
>= 5%	120	89 (74.2)	2.46 (1.84, 3.71)	104	57 (54.8)	6.11 (3.75, 9.00)	1.435 (1.025, 2.010) 0.0344	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:08

4.1.8 Subgruppenanalysen – Zeit bis zum ersten Auftreten von zum Therapieabbruch führenden UE

Protocol: CA209648 Page 1 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	48 (30.4)	21.19 (12.45, N.A.)	145	31 (21.4)	14.23 (10.09, N.A.)	1.143 (0.717, 1.821) 0.5741	
AGE								0.2290
< 65	95	21 (22.1)	N.A. (14.55, N.A.)	75	17 (22.7)	14.23 (10.09, N.A.)	0.771 (0.400, 1.489) 0.4392	
>= 65 AND < 75	55	23 (41.8)	10.84 (5.52, N.A.)	58	11 (19.0)	N.A. (7.75, N.A.)	2.070 (0.998, 4.292) 0.0459	
>= 75	8	4 (50.0)	16.62 (0.95, N.A.)	12	3 (25.0)	N.A. (3.02, N.A.)	0.570 (0.083, 3.887) 0.5621	
SEX								0.8851
MALE	131	41 (31.3)	19.12 (10.91, N.A.)	122	26 (21.3)	14.23 (10.09, N.A.)	1.120 (0.671, 1.867) 0.6648	
FEMALE	27	7 (25.9)	N.A. (8.41, N.A.)	23	5 (21.7)	N.A. (7.75, N.A.)	1.239 (0.392, 3.911) 0.7186	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 2 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9854
ASIAN	117	35 (29.9)	21.19 (13.31, N.A.)	104	22 (21.2)	N.A. (10.09, N.A.)	1.167 (0.674, 2.022) 0.5814	
NON-ASIAN	41	13 (31.7)	14.55 (8.25, N.A.)	41	9 (22.0)	14.23 (14.23, N.A.)	1.101 (0.459, 2.643) 0.8298	
REGION (PER CRF)								0.7988
J/K/T	91	30 (33.0)	21.19 (12.45, N.A.)	85	21 (24.7)	10.45 (8.25, N.A.)	1.112 (0.624, 1.982) 0.7187	
REST OF ASIA	25	4 (16.0)	N.A. (6.54, N.A.)	19	1 (5.3)	N.A.	2.632 (0.294, 23.589) 0.3687	
REST OF WORLD	42	14 (33.3)	14.55 (8.25, N.A.)	41	9 (22.0)	14.23 (14.23, N.A.)	1.112 (0.469, 2.638) 0.8087	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 3 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9187
ASIA	116	34 (29.3)	N.A. (13.31, N.A.)	104	22 (21.2)	N.A. (10.09, N.A.)	1.158 (0.666, 2.013) 0.6030	
NON-ASIA	42	14 (33.3)	14.55 (8.25, N.A.)	41	9 (22.0)	14.23 (14.23, N.A.)	1.112 (0.469, 2.638) 0.8087	
ECOG PS (PER CRF)								0.7781
0	71	22 (31.0)	21.19 (12.45, N.A.)	69	16 (23.2)	14.23 (8.25, N.A.)	1.065 (0.550, 2.065) 0.8505	
1	87	26 (29.9)	19.12 (9.66, N.A.)	74	14 (18.9)	N.A. (10.09, N.A.)	1.307 (0.668, 2.558) 0.4346	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 4 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
WEIGHT								0.3250
< 60 KG	96	31 (32.3)	16.62 (9.66, N.A.)	76	15 (19.7)	N.A. (10.09, N.A.)	1.299 (0.687, 2.457) 0.4204	
>= 60 KG	62	17 (27.4)	N.A. (10.84, N.A.)	69	16 (23.2)	14.23 (7.56, N.A.)	0.992 (0.494, 1.992) 0.9824	
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9810
STAGE I	5	2 (40.0)	19.12 (5.59, N.A.)	5	2 (40.0)	7.29 (4.63, N.A.)	0.390 (0.034, 4.438) 0.4328	
STAGE II	5	2 (40.0)	6.87 (2.30, N.A.)	5	0	N.E.	N.E. 0.2087	
STAGE III	33	11 (33.3)	N.A. (5.52, N.A.)	46	11 (23.9)	14.23 (8.25, N.A.)	1.162 (0.492, 2.744) 0.7298	
STAGE IV	114	33 (28.9)	21.19 (10.91, N.A.)	89	18 (20.2)	N.A. (10.09, N.A.)	1.169 (0.646, 2.116) 0.6055	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 5 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.4250
GX	11	1 (9.1)	N.A. (0.95, N.A.)	14	2 (14.3)	N.A. (4.63, N.A.)	0.878 (0.079, 9.776) 0.9155	
G1	8	3 (37.5)	N.A. (3.32, N.A.)	8	3 (37.5)	N.A. (0.39, N.A.)	0.785 (0.158, 3.904) 0.7670	
G2	58	20 (34.5)	14.55 (8.25, N.A.)	50	7 (14.0)	N.A. (10.09, N.A.)	2.020 (0.843, 4.838) 0.1079	
G3	28	9 (32.1)	N.A. (9.66, N.A.)	36	9 (25.0)	N.A. (7.75, N.A.)	1.015 (0.385, 2.672) 0.9767	
NOT OTHERWISE SPECIFIED	51	15 (29.4)	19.12 (12.45, N.A.)	37	10 (27.0)	10.45 (6.97, N.A.)	0.863 (0.374, 1.992) 0.7301	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 6 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9455
UPPER THORACIC	37	11 (29.7)	12.45 (8.02, N.A.)	25	4 (16.0)	N.A. (10.45, N.A.)	1.397 (0.436, 4.477) 0.5720	
MIDDLE THORACIC	50	18 (36.0)	21.19 (5.98, N.A.)	52	15 (28.8)	10.09 (7.29, N.A.)	1.290 (0.643, 2.587) 0.4718	
LOWER THORACIC	59	16 (27.1)	N.A. (13.31, N.A.)	60	12 (20.0)	14.23 (14.23, N.A.)	1.060 (0.486, 2.311) 0.8832	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	14.55 (9.66, N.A.)	8	0	N.E.	N.E. N.A.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 7 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.8375
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	19.12 (1.74, N.A.)	13	4 (30.8)	14.23 (4.63, N.A.)	0.310 (0.034, 2.792) 0.2697	
RECURRENT - DISTANT	25	6 (24.0)	N.A. (6.87, N.A.)	27	3 (11.1)	N.A. (7.29, N.A.)	2.010 (0.501, 8.072) 0.3151	
DE NOVO METASTATIC	107	31 (29.0)	21.19 (12.45, N.A.)	81	16 (19.8)	N.A.	1.252 (0.674, 2.326) 0.4760	
UNRESECTABLE ADVANCED	18	9 (50.0)	9.66 (5.29, N.A.)	24	8 (33.3)	8.25 (7.56, N.A.)	1.055 (0.397, 2.804) 0.9096	
SMOKING STATUS								0.3425
CURRENT/FORMER	136	46 (33.8)	16.62 (10.84, N.A.)	111	26 (23.4)	14.23 (8.25, N.A.)	1.136 (0.691, 1.870) 0.6141	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	5 (14.7)	N.A. (10.09, N.A.)	0.616 (0.119, 3.197) 0.5600	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 8 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.4181
CURRENT/FORMER	126	40 (31.7)	21.19 (10.91, N.A.)	117	24 (20.5)	14.23 (10.45, N.A.)	1.257 (0.746, 2.118) 0.3888	
NEVER/UNKNOWN	32	8 (25.0)	N.A. (8.02, N.A.)	28	7 (25.0)	10.09 (6.97, N.A.)	0.796 (0.281, 2.255) 0.6671	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9057
<= 1	80	33 (41.3)	14.55 (6.87, N.A.)	69	21 (30.4)	10.45 (7.75, N.A.)	1.184 (0.675, 2.077) 0.5558	
>= 2	78	15 (19.2)	N.A. (13.31, N.A.)	76	10 (13.2)	N.A.	1.124 (0.490, 2.576) 0.7821	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 9 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.4485
< 1 YEAR	128	41 (32.0)	21.19 (10.91, N.A.)	115	24 (20.9)	N.A. (10.09, N.A.)	1.248 (0.743, 2.097) 0.4012	
1 - < 3 YEARS	25	4 (16.0)	N.A. (6.87, N.A.)	21	4 (19.0)	14.23 (7.29, N.A.)	0.729 (0.180, 2.957) 0.6569	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9945
YES	38	9 (23.7)	N.A. (9.66, N.A.)	37	6 (16.2)	14.23 (10.45, N.A.)	0.991 (0.340, 2.890) 0.9871	
NO	120	39 (32.5)	16.62 (10.91, N.A.)	108	25 (23.1)	N.A. (10.09, N.A.)	1.198 (0.715, 2.009) 0.4916	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 10 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.8804
YES	26	6 (23.1)	N.A. (6.87, N.A.)	27	5 (18.5)	14.23 (10.45, N.A.)	0.858 (0.242, 3.044) 0.8134	
NO	132	42 (31.8)	21.19 (10.91, N.A.)	118	26 (22.0)	N.A. (10.09, N.A.)	1.185 (0.717, 1.959) 0.5079	
PD-L1 CPS I								0.9777
< 10	53	15 (28.3)	19.12 (8.02, N.A.)	54	10 (18.5)	N.A.	1.102 (0.480, 2.531) 0.8188	
>= 10	92	31 (33.7)	N.A. (10.84, N.A.)	89	21 (23.6)	10.45 (8.25, N.A.)	1.228 (0.693, 2.176) 0.4812	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 11 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.1762
< 5	29	6 (20.7)	21.19 (6.54, N.A.)	24	6 (25.0)	N.A.	0.467 (0.131, 1.667) 0.2300	
>= 5	116	40 (34.5)	19.12 (10.84, N.A.)	119	25 (21.0)	14.23 (10.09, N.A.)	1.388 (0.831, 2.316) 0.2084	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.8677
< 10%	55	19 (34.5)	13.31 (8.25, N.A.)	57	12 (21.1)	N.A. (14.23, N.A.)	1.146 (0.545, 2.409) 0.7192	
>= 10%	103	29 (28.2)	N.A. (14.55, N.A.)	88	19 (21.6)	N.A. (8.25, N.A.)	1.146 (0.631, 2.082) 0.6564	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

Protocol: CA209648 Page 12 of 12

Adverse Events Leading to Discontinuation of Study Treatment: Subgroup Time-Adjusted Analyses
Excluding Progression Terms
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

AEs Leading to Discontinuation of Study Treatment Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.3322
< 5%	38	12 (31.6)	10.91 (8.02, N.A.)	41	6 (14.6)	14.23 (14.23, N.A.)	1.516 (0.552, 4.165) 0.4166	
>= 5%	120	36 (30.0)	N.A. (13.31, N.A.)	104	25 (24.0)	N.A. (8.25, N.A.)	1.066 (0.630, 1.805) 0.8107	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubaehr-ebr503.sas 02MAR2022:08:33:20

4.2 Zusatzanalysen Unerwünschte Ereignisse auf SOC/PT-Ebene

4.2.1 Zeit bis zum ersten Auftreten von jeglichen UE auf SOC/PT-Ebene

Protocol: CA209648 Page 1 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
TOTAL SUBJECTS WITH AN EVENT	158	157 (99.4)	0.39 (0.26, 0.46)	145	144 (99.3)	0.10 (0.07, 0.10)	0.515 (0.405, 0.654)	<0.0001
GASTROINTESTINAL DISORDERS	158	123 (77.8)	2.23 (1.58, 3.48)	145	132 (91.0)	0.20 (0.13, 0.23)	0.368 (0.284, 0.477)	<0.0001
CONSTIPATION	158	50 (31.6)	N.A. (12.98, N.A.)	145	68 (46.9)	5.85 (3.38, N.A.)	0.491 (0.339, 0.712)	0.0001
DIARRHOEA	158	48 (30.4)	N.A. (9.69, N.A.)	145	25 (17.2)	N.A. (15.28, N.A.)	1.781 (1.096, 2.894)	0.0181
NAUSEA	158	46 (29.1)	N.A. (13.60, N.A.)	145	84 (57.9)	2.17 (1.02, 5.45)	0.333 (0.231, 0.480)	<0.0001
VOMITING	158	31 (19.6)	N.A. (25.07, N.A.)	145	31 (21.4)	N.A.	0.792 (0.478, 1.314)	0.3694
DYSPHAGIA	158	19 (12.0)	N.A.	145	24 (16.6)	N.A. (11.43, N.A.)	0.588 (0.312, 1.106)	0.0959
STOMATITIS	158	19 (12.0)	N.A.	145	34 (23.4)	N.A.	0.445 (0.253, 0.786)	0.0041

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

Protocol: CA209648 Page 2 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
ABDOMINAL PAIN	158	13 (8.2)	N.A.	145	12 (8.3)	N.A.	1.006 (0.457, 2.215)	0.9873
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	158	94 (59.5)	3.98 (2.66, 6.37)	145	99 (68.3)	1.97 (1.12, 2.92)	0.649 (0.485, 0.867)	0.0035
PYREXIA	158	44 (27.8)	N.A. (24.02, N.A.)	145	22 (15.2)	N.A.	1.952 (1.164, 3.274)	0.0099
FATIGUE	158	27 (17.1)	N.A.	145	26 (17.9)	N.A. (15.21, N.A.)	0.807 (0.466, 1.398)	0.4472
MALAISE	158	19 (12.0)	N.A.	145	32 (22.1)	N.A.	0.506 (0.286, 0.895)	0.0172
OEDEMA PERIPHERAL	158	12 (7.6)	N.A.	145	6 (4.1)	N.A.	1.503 (0.545, 4.144)	0.4284
ASTHENIA	158	11 (7.0)	N.A.	145	12 (8.3)	N.A.	0.787 (0.339, 1.829)	0.5783
MUCOSAL INFLAMMATION	158	1 (0.6)	N.A.	145	19 (13.1)	N.A.	<0.001 (<0.001, N.A.)	<0.0001

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 3 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	P-value (3)
METABOLISM AND NUTRITION DISORDERS	158	93 (58.9)	4.73 (3.29, 6.54)	145	105 (72.4)	0.99 (0.43, 2.56)	0.526 (0.395, 0.701)	<0.0001
DECREASED APPETITE	158	36 (22.8)	N.A. (16.13, N.A.)	145	80 (55.2)	3.91 (1.05, 10.18)	0.258 (0.172, 0.388)	<0.0001
HYPOKALAEMIA	158	20 (12.7)	N.A.	145	16 (11.0)	N.A.	1.190 (0.616, 2.299)	0.6050
HYPONATRAEMIA	158	19 (12.0)	N.A.	145	15 (10.3)	N.A.	1.115 (0.559, 2.223)	0.7560
HYPOALBUMINAEMIA	158	15 (9.5)	N.A.	145	7 (4.8)	N.A.	1.974 (0.795, 4.900)	0.1355
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	158	87 (55.1)	3.91 (2.79, 8.38)	145	44 (30.3)	N.A. (8.44, N.A.)	2.341 (1.619, 3.386)	<0.0001
RASH	158	42 (26.6)	N.A.	145	10 (6.9)	N.A.	4.581 (2.292, 9.154)	<0.0001
PRURITUS	158	35 (22.2)	N.A. (21.19, N.A.)	145	7 (4.8)	N.A.	4.876 (2.150, 11.061)	<0.0001

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

Protocol: CA209648 Page 4 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
DRY SKIN	158	10 (6.3)	N.A.	145	3 (2.1)	N.A.	2.977 (0.805, 11.012)	0.0862
RASH MACULO-PAPULAR	158	10 (6.3)	N.A.	145	2 (1.4)	N.A.	4.869 (1.066, 22.252)	0.0238
ALOPECIA	158	8 (5.1)	N.A.	145	21 (14.5)	N.A.	0.233 (0.094, 0.580)	0.0006
INVESTIGATIONS	158	79 (50.0)	5.72 (3.58, 15.64)	145	76 (52.4)	4.57 (2.96, 8.25)	0.841 (0.609, 1.162)	0.2894
ASPARTATE AMINOTRANSFERASE INCREASED	158	31 (19.6)	N.A.	145	4 (2.8)	N.A.	7.268 (2.554, 20.685)	<0.0001
ALANINE AMINOTRANSFERASE INCREASED	158	28 (17.7)	N.A.	145	5 (3.4)	N.A.	5.376 (2.068, 13.977)	0.0001
WEIGHT DECREASED	158	20 (12.7)	N.A.	145	17 (11.7)	N.A.	1.093 (0.570, 2.096)	0.7889
NEUTROPHIL COUNT DECREASED	158	8 (5.1)	N.A.	145	23 (15.9)	N.A.	0.259 (0.115, 0.586)	0.0005

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

Protocol: CA209648 Page 5 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
BLOOD CREATININE INCREASED	158	6 (3.8)	N.A.	145	21 (14.5)	N.A.	0.234 (0.094, 0.583)	0.0007
WHITE BLOOD CELL COUNT DECREASED	158	5 (3.2)	N.A.	145	20 (13.8)	N.A.	0.214 (0.080, 0.572)	0.0007
PLATELET COUNT DECREASED	158	4 (2.5)	N.A.	145	13 (9.0)	N.A.	0.222 (0.069, 0.713)	0.0061
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	158	70 (44.3)	8.97 (6.11, 20.01)	145	62 (42.8)	N.A. (5.13, N.A.)	0.894 (0.632, 1.263)	0.5355
COUGH	158	22 (13.9)	N.A.	145	16 (11.0)	N.A.	1.183 (0.615, 2.277)	0.6142
DYSPNOEA	158	15 (9.5)	N.A.	145	6 (4.1)	N.A. (14.46, N.A.)	2.257 (0.866, 5.881)	0.0869
PNEUMONIA ASPIRATION	158	13 (8.2)	N.A.	145	7 (4.8)	N.A.	1.642 (0.648, 4.162)	0.2916
PNEUMONITIS	158	12 (7.6)	N.A.	145	3 (2.1)	N.A.	3.414 (0.945, 12.337)	0.0467

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

Protocol: CA209648 Page 6 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	P-value (3)
PRODUCTIVE COUGH	158	10 (6.3)	N.A.	145	6 (4.1)	N.A.	1.464 (0.523, 4.097)	0.4654
HICCUPS	158	8 (5.1)	N.A.	145	30 (20.7)	N.A.	0.226 (0.103, 0.492)	<0.0001
INFECTIONS AND INFESTATIONS	158	69 (43.7)	8.97 (5.55, 20.60)	145	48 (33.1)	10.84 (8.67, N.A.)	1.399 (0.964, 2.030)	0.0762
PNEUMONIA	158	24 (15.2)	N.A.	145	19 (13.1)	N.A.	1.035 (0.559, 1.917)	0.9146
BLOOD AND LYMPHATIC SYSTEM DISORDERS	158	57 (36.1)	18.60 (12.94, N.A.)	145	63 (43.4)	8.61 (4.57, N.A.)	0.711 (0.492, 1.028)	0.0668
ANAEMIA	158	44 (27.8)	N.A. (18.60, N.A.)	145	54 (37.2)	N.A. (6.87, N.A.)	0.647 (0.430, 0.974)	0.0354
NEUTROPENIA	158	2 (1.3)	N.A.	145	11 (7.6)	N.A.	0.073 (0.009, 0.577)	0.0015
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	158	49 (31.0)	N.A. (17.15, N.A.)	145	46 (31.7)	N.A. (7.39, N.A.)	0.976 (0.650, 1.468)	0.9074

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

Protocol: CA209648 Page 7 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
MALIGNANT NEOPLASM PROGRESSION	158	34 (21.5)	N.A.	145	33 (22.8)	N.A.	0.927 (0.570, 1.508)	0.7623
CANCER PAIN	158	10 (6.3)	N.A.	145	10 (6.9)	N.A.	0.894 (0.368, 2.172)	0.8045
ENDOCRINE DISORDERS	158	47 (29.7)	N.A. (14.55, N.A.)	145	3 (2.1)	N.A.	16.973 (5.270, 54.670)	<0.0001
HYPOTHYROIDISM	158	24 (15.2)	N.A.	145	0	N.E.	N.E.	<0.0001
HYPERTHYROIDISM	158	13 (8.2)	N.A.	145	1 (0.7)	N.A.	13.264 (1.732,>99.999)	0.0012
ADRENAL INSUFFICIENCY	158	10 (6.3)	N.A.	145	1 (0.7)	N.A.	7.916 (1.002, 62.532)	0.0205
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	158	43 (27.2)	N.A. (15.77, N.A.)	145	28 (19.3)	N.A. (10.02, N.A.)	1.482 (0.917, 2.395)	0.1064
ARTHRALGIA	158	12 (7.6)	N.A.	145	8 (5.5)	N.A.	1.084 (0.423, 2.778)	0.8656

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

Protocol: CA209648 Page 8 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	P-value (3)
NERVOUS SYSTEM DISORDERS	158	36 (22.8)	N.A. (24.94, N.A.)	145	59 (40.7)	9.17 (5.95, N.A.)	0.444 (0.289, 0.681)	0.0001
HEADACHE	158	12 (7.6)	N.A.	145	6 (4.1)	N.A.	1.708 (0.635, 4.592)	0.2827
DIZZINESS	158	10 (6.3)	N.A.	145	14 (9.7)	N.A.	0.595 (0.263, 1.347)	0.2079
DYSGEUSIA	158	5 (3.2)	N.A.	145	10 (6.9)	N.A.	0.445 (0.152, 1.304)	0.1291
PERIPHERAL SENSORY NEUROPATHY	158	3 (1.9)	N.A.	145	11 (7.6)	N.A.	0.236 (0.065, 0.849)	0.0163
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	158	31 (19.6)	N.A.	145	19 (13.1)	N.A. (14.95, N.A.)	1.487 (0.832, 2.658)	0.1790
PSYCHIATRIC DISORDERS	158	25 (15.8)	N.A.	145	28 (19.3)	N.A.	0.807 (0.469, 1.389)	0.4391
INSOMNIA	158	16 (10.1)	N.A.	145	19 (13.1)	N.A.	0.765 (0.392, 1.496)	0.4349

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

Protocol: CA209648 Page 9 of 9

Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
HEPATOBILIARY DISORDERS	158	17 (10.8)	N.A.	145	5 (3.4)	N.A.	2.671 (0.971, 7.346)	0.0483
HEPATIC FUNCTION ABNORMAL	158	10 (6.3)	N.A.	145	1 (0.7)	N.A.	7.615 (0.960, 60.405)	0.0243
VASCULAR DISORDERS	158	17 (10.8)	N.A.	145	29 (20.0)	N.A.	0.505 (0.276, 0.925)	0.0243
HYPERTENSION	158	5 (3.2)	N.A.	145	11 (7.6)	N.A.	0.367 (0.124, 1.088)	0.0604
CARDIAC DISORDERS	158	13 (8.2)	N.A.	145	10 (6.9)	N.A.	1.137 (0.496, 2.608)	0.7615
EYE DISORDERS	158	12 (7.6)	N.A.	145	6 (4.1)	N.A.	1.454 (0.524, 4.033)	0.4696
RENAL AND URINARY DISORDERS	158	12 (7.6)	N.A.	145	30 (20.7)	N.A.	0.315 (0.159, 0.621)	0.0004
EAR AND LABYRINTH DISORDERS	158	2 (1.3)	N.A.	145	11 (7.6)	N.A.	0.150 (0.033, 0.683)	0.0048

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:07

4.2.2 Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3) auf SOC/PT-Ebene

Protocol: CA209648 Page 1 of 3

Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
TOTAL SUBJECTS WITH AN EVENT	158	125 (79.1)	3.19 (2.20, 3.78)	145	112 (77.2)	2.96 (1.87, 3.75)	0.841 (0.648, 1.093)	0.1955
GASTROINTESTINAL DISORDERS	158	40 (25.3)	N.A. (13.04, N.A.)	145	44 (30.3)	N.A.	0.744 (0.483, 1.146)	0.1772
DYSPHAGIA	158	10 (6.3)	N.A.	145	10 (6.9)	N.A.	0.806 (0.326, 1.989)	0.6391
DIARRHOEA	158	8 (5.1)	N.A.	145	2 (1.4)	N.A.	3.644 (0.773, 17.181)	0.0805
VOMITING	158	5 (3.2)	N.A.	145	8 (5.5)	N.A.	0.378 (0.111, 1.291)	0.1083
METABOLISM AND NUTRITION DISORDERS	158	37 (23.4)	N.A. (17.05, N.A.)	145	32 (22.1)	N.A.	0.863 (0.527, 1.412)	0.5581
HYPOKALAEMIA	158	9 (5.7)	N.A.	145	8 (5.5)	N.A.	1.082 (0.417, 2.808)	0.8710
HYPONATRAEMIA	158	8 (5.1)	N.A.	145	6 (4.1)	N.A.	1.039 (0.343, 3.153)	0.9455

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:19

Protocol: CA209648 Page 2 of 3

Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
DECREASED APPETITE	158	5 (3.2)	N.A.	145	10 (6.9)	N.A.	0.415 (0.139, 1.242)	0.1054
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	158	36 (22.8)	N.A.	145	37 (25.5)	N.A. (9.63, N.A.)	0.870 (0.546, 1.386)	0.5606
MALIGNANT NEOPLASM PROGRESSION	158	31 (19.6)	N.A.	145	32 (22.1)	N.A.	0.857 (0.518, 1.417)	0.5495
INFECTIONS AND INFESTATIONS	158	34 (21.5)	N.A.	145	18 (12.4)	N.A.	1.663 (0.935, 2.958)	0.0806
PNEUMONIA	158	18 (11.4)	N.A.	145	11 (7.6)	N.A.	1.528 (0.721, 3.239)	0.2650
BLOOD AND LYMPHATIC SYSTEM DISORDERS	158	26 (16.5)	N.A. (24.18, N.A.)	145	38 (26.2)	N.A.	0.504 (0.299, 0.848)	0.0086
ANAEMIA	158	16 (10.1)	N.A.	145	26 (17.9)	N.A.	0.486 (0.253, 0.932)	0.0265
INVESTIGATIONS	158	26 (16.5)	N.A.	145	31 (21.4)	N.A.	0.638 (0.374, 1.091)	0.0980

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:19

Protocol: CA209648 Page 3 of 3

Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
NEUTROPHIL COUNT DECREASED	158	4 (2.5)	N.A.	145	13 (9.0)	N.A.	0.238 (0.076, 0.746)	0.0077
WHITE BLOOD CELL COUNT DECREASED	158	3 (1.9)	N.A.	145	8 (5.5)	N.A.	0.350 (0.093, 1.321)	0.1050
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	158	19 (12.0)	N.A.	145	13 (9.0)	N.A.	1.270 (0.621, 2.598)	0.5114
PNEUMONIA ASPIRATION	158	8 (5.1)	N.A.	145	3 (2.1)	N.A.	2.314 (0.612, 8.744)	0.2031
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	158	15 (9.5)	N.A.	145	15 (10.3)	N.A.	0.698 (0.331, 1.473)	0.3426
ENDOCRINE DISORDERS	158	12 (7.6)	N.A.	145	1 (0.7)	N.A.	10.700 (1.378, 83.085)	0.0047
HEPATOBILIARY DISORDERS	158	10 (6.3)	N.A.	145	3 (2.1)	N.A.	3.110 (0.853, 11.338)	0.0700
NERVOUS SYSTEM DISORDERS	158	3 (1.9)	N.A.	145	8 (5.5)	N.A.	0.284 (0.075, 1.082)	0.0496

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:19

4.2.3 Zeit bis zum ersten Auftreten von SUE auf SOC/PT-Ebene

Protocol: CA209648 Page 1 of 2

Serious Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
TOTAL SUBJECTS WITH AN EVENT	158	122 (77.2)	2.40 (1.87, 3.48)	145	90 (62.1)	5.22 (3.75, 6.41)	1.299 (0.985, 1.714)	0.0633
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	158	38 (24.1)	N.A.	145	35 (24.1)	N.A.	0.963 (0.604, 1.537)	0.8774
MALIGNANT NEOPLASM PROGRESSION	158	31 (19.6)	N.A.	145	31 (21.4)	N.A.	0.888 (0.535, 1.474)	0.6497
GASTROINTESTINAL DISORDERS	158	30 (19.0)	N.A. (25.63, N.A.)	145	34 (23.4)	N.A. (12.22, N.A.)	0.734 (0.445, 1.211)	0.2251
DYSPHAGIA	158	6 (3.8)	N.A.	145	12 (8.3)	N.A. (12.22, N.A.)	0.393 (0.144, 1.075)	0.0603
VOMITING	158	3 (1.9)	N.A.	145	9 (6.2)	N.A.	0.251 (0.066, 0.957)	0.0299
INFECTIONS AND INFESTATIONS	158	24 (15.2)	N.A.	145	18 (12.4)	N.A.	1.084 (0.581, 2.023)	0.8011
PNEUMONIA	158	13 (8.2)	N.A.	145	13 (9.0)	N.A.	0.859 (0.391, 1.884)	0.7035

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:29

Protocol: CA209648 Page 2 of 2

Serious Adverse Events: Time-Adjusted Analyses
by SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	158	22 (13.9)	N.A.	145	10 (6.9)	N.A.	1.949 (0.916, 4.145)	0.0775
PNEUMONIA ASPIRATION	158	10 (6.3)	N.A.	145	4 (2.8)	N.A.	2.221 (0.695, 7.097)	0.1670
METABOLISM AND NUTRITION DISORDERS	158	21 (13.3)	N.A.	145	15 (10.3)	N.A.	1.101 (0.558, 2.174)	0.7810
ENDOCRINE DISORDERS	158	18 (11.4)	N.A.	145	1 (0.7)	N.A.	15.868 (2.102,>99.999)	0.0003
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	158	16 (10.1)	N.A.	145	9 (6.2)	N.A.	1.561 (0.682, 3.572)	0.2880
BLOOD AND LYMPHATIC SYSTEM DISORDERS	158	12 (7.6)	N.A.	145	9 (6.2)	N.A.	0.968 (0.392, 2.393)	0.9419

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-taesocpthr-ebr503.sas 07FEB2022:09:17:29

4.2.4 Zum Therapieabbruch führende UE auf SOC/PT-Ebene (deskriptive Analyse)

Protocol: CA209648 Page 1 of 4

Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N = 158			Chemotherapy N = 145		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	51 (32.3)	34 (21.5)	1 (0.6)	34 (23.4)	14 (9.7)	0
Respiratory, thoracic and mediastinal disorders	11 (7.0)	6 (3.8)	1 (0.6)	3 (2.1)	3 (2.1)	0
Pneumonitis	6 (3.8)	3 (1.9)	0	0	0	0
Interstitial lung disease	2 (1.3)	2 (1.3)	0	0	0	0
Acute respiratory distress syndrome	1 (0.6)	1 (0.6)	0	0	0	0
Pneumonia aspiration	1 (0.6)	0	0	2 (1.4)	2 (1.4)	0
Respiratory failure	1 (0.6)	0	1 (0.6)	0	0	0
Bronchial obstruction	0	0	0	1 (0.7)	1 (0.7)	0
Endocrine disorders	7 (4.4)	6 (3.8)	0	0	0	0
Adrenal insufficiency	3 (1.9)	3 (1.9)	0	0	0	0
Hypophysitis	2 (1.3)	2 (1.3)	0	0	0	0
Hypothyroidism	2 (1.3)	0	0	0	0	0
Hypopituitarism	1 (0.6)	1 (0.6)	0	0	0	0
Inappropriate antidiuretic hormone secretion	1 (0.6)	0	0	0	0	0
Investigations	7 (4.4)	5 (3.2)	0	9 (6.2)	0	0
Aspartate aminotransferase increased	4 (2.5)	2 (1.3)	0	0	0	0
Alanine aminotransferase increased	3 (1.9)	2 (1.3)	0	0	0	0
Blood creatine phosphokinase increased	1 (0.6)	1 (0.6)	0	0	0	0
Gamma-glutamyltransferase increased	1 (0.6)	0	0	0	0	0
Transaminases increased	1 (0.6)	0	0	0	0	0
Blood creatinine increased	0	0	0	5 (3.4)	0	0
Creatinine renal clearance decreased	0	0	0	3 (2.1)	0	0
Weight decreased	0	0	0	1 (0.7)	0	0
Gastrointestinal disorders	6 (3.8)	5 (3.2)	0	4 (2.8)	3 (2.1)	0

Oct 2021 DBL.
Includes events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 24.0; CTC Version: 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltdcat-648-ebr503-batch1.sas 07FEB2022:08:44:15

Protocol: CA209648 Page 2 of 4

Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%)	Nivo + Ipi N = 158			Chemotherapy N = 145		
Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Colitis	1 (0.6)	1 (0.6)	0	0	0	0
Enteritis	1 (0.6)	1 (0.6)	0	0	0	0
Gastritis	1 (0.6)	1 (0.6)	0	0	0	0
Mouth ulceration	1 (0.6)	0	0	0	0	0
Pancreatitis	1 (0.6)	1 (0.6)	0	0	0	0
Pancreatitis acute	1 (0.6)	1 (0.6)	0	0	0	0
Oesophageal motility disorder	0	0	0	1 (0.7)	1 (0.7)	0
Oesophageal stenosis	0	0	0	2 (1.4)	1 (0.7)	0
Vomiting	0	0	0	1 (0.7)	1 (0.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (3.8)	3 (1.9)	0	4 (2.8)	3 (2.1)	0
Malignant neoplasm progression	3 (1.9)	2 (1.3)	0	3 (2.1)	2 (1.4)	0
Adult T-cell lymphoma/leukaemia	1 (0.6)	1 (0.6)	0	0	0	0
Colorectal cancer	1 (0.6)	0	0	0	0	0
Gastric cancer	1 (0.6)	0	0	0	0	0
Metastases to meninges	0	0	0	1 (0.7)	1 (0.7)	0
Hepatobiliary disorders	5 (3.2)	5 (3.2)	0	0	0	0
Hepatic function abnormal	2 (1.3)	2 (1.3)	0	0	0	0
Autoimmune hepatitis	1 (0.6)	1 (0.6)	0	0	0	0
Hyperbilirubinaemia	1 (0.6)	1 (0.6)	0	0	0	0
Immune-mediated hepatitis	1 (0.6)	1 (0.6)	0	0	0	0
Metabolism and nutrition disorders	3 (1.9)	3 (1.9)	0	2 (1.4)	1 (0.7)	0
Fulminant type 1 diabetes mellitus	1 (0.6)	1 (0.6)	0	0	0	0
Hyponatraemia	1 (0.6)	1 (0.6)	0	0	0	0
Type 1 diabetes mellitus	1 (0.6)	1 (0.6)	0	0	0	0
Decreased appetite	0	0	0	1 (0.7)	0	0

Oct 2021 DBL.
Includes events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 24.0; CTC Version: 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltdcat-648-ebr503-batch1.sas 07FEB2022:08:44:15

Protocol: CA209648 Page 3 of 4

Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%)	Nivo + Ipi N = 158			Chemotherapy N = 145		
Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Dehydration	0	0	0	1 (0.7)	1 (0.7)	0
Blood and lymphatic system disorders	2 (1.3)	0	0	0	0	0
Anaemia	1 (0.6)	0	0	0	0	0
Immune thrombocytopenia	1 (0.6)	0	0	0	0	0
Renal and urinary disorders	2 (1.3)	0	0	7 (4.8)	1 (0.7)	0
Acute kidney injury	1 (0.6)	0	0	0	0	0
Tubulointerstitial nephritis	1 (0.6)	0	0	0	0	0
Chronic kidney disease	0	0	0	1 (0.7)	0	0
Renal failure	0	0	0	3 (2.1)	1 (0.7)	0
Renal impairment	0	0	0	3 (2.1)	0	0
Skin and subcutaneous tissue disorders	2 (1.3)	2 (1.3)	0	0	0	0
Erythema multiforme	1 (0.6)	1 (0.6)	0	0	0	0
Rash maculo-papular	1 (0.6)	1 (0.6)	0	0	0	0
Cardiac disorders	1 (0.6)	0	0	1 (0.7)	0	0
Myocarditis	1 (0.6)	0	0	0	0	0
Cardiotoxicity	0	0	0	1 (0.7)	0	0
Eye disorders	1 (0.6)	1 (0.6)	0	0	0	0
Uveitis	1 (0.6)	1 (0.6)	0	0	0	0
General disorders and administration site conditions	1 (0.6)	1 (0.6)	0	2 (1.4)	1 (0.7)	0
General physical health deterioration	1 (0.6)	1 (0.6)	0	1 (0.7)	1 (0.7)	0
Malaise	0	0	0	1 (0.7)	0	0

Oct 2021 DBL.
Includes events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 24.0; CTC Version: 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltdcat-648-ebr503-batch1.sas 07FEB2022:08:44:15

Protocol: CA209648 Page 4 of 4

Adverse Events Leading to Discontinuation of Study Treatment Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

System Organ Class (%)	Nivo + Ipi N = 158			Chemotherapy N = 145		
Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Infections and infestations	1 (0.6)	1 (0.6)	0	1 (0.7)	0	0
Pneumonia	1 (0.6)	1 (0.6)	0	0	0	0
Bronchitis	0	0	0	1 (0.7)	0	0
Musculoskeletal and connective tissue disorders	1 (0.6)	0	0	0	0	0
Immune-mediated arthritis	1 (0.6)	0	0	0	0	0
Nervous system disorders	1 (0.6)	0	0	4 (2.8)	2 (1.4)	0
Cerebral infarction	1 (0.6)	0	0	0	0	0
Neuropathy peripheral	0	0	0	1 (0.7)	0	0
Paraesthesia	0	0	0	1 (0.7)	1 (0.7)	0
Peripheral sensory neuropathy	0	0	0	2 (1.4)	1 (0.7)	0
Ear and labyrinth disorders	0	0	0	1 (0.7)	0	0
Deafness neurosensory	0	0	0	1 (0.7)	0	0
Hypoacusis	0	0	0	1 (0.7)	0	0
Injury, poisoning and procedural complications	0	0	0	1 (0.7)	0	0
Infusion related reaction	0	0	0	1 (0.7)	0	0

Oct 2021 DBL.
Includes events reported between the first dose and 100 days after the last dose of the study therapy.
MedDRA Version: 24.0; CTC Version: 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltdcat-648-ebr503-batch1.sas 07FEB2022:08:44:15

4.2.5 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen UE auf SOC/PT-Ebene

Protocol: CA209648 Page 1 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	123 (77.8)	2.23 (1.58, 3.48)	145	132 (91.0)	0.20 (0.13, 0.23)	0.375 (0.290, 0.484) <0.0001	
AGE								0.5297
< 65	95	75 (78.9)	2.00 (1.35, 3.71)	75	68 (90.7)	0.23 (0.10, 0.43)	0.427 (0.305, 0.599) <0.0001	
>= 65 AND < 75	55	41 (74.5)	2.20 (0.62, 4.93)	58	53 (91.4)	0.13 (0.10, 0.26)	0.323 (0.210, 0.498) <0.0001	
>= 75	8	7 (87.5)	3.06 (0.13, N.A.)	12	11 (91.7)	0.20 (0.07, 1.08)	0.353 (0.125, 0.994) 0.0420	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 2 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1579
MALE	131	101 (77.1)	2.56 (1.61, 3.71)	122	110 (90.2)	0.20 (0.13, 0.26)	0.395 (0.299, 0.523) <0.0001	
FEMALE	27	22 (81.5)	2.00 (0.56, 5.03)	23	22 (95.7)	0.10 (0.07, 0.23)	0.254 (0.130, 0.494) <0.0001	
RACE								0.3787
ASIAN	117	91 (77.8)	2.23 (1.41, 3.58)	104	97 (93.3)	0.16 (0.10, 0.23)	0.344 (0.255, 0.465) <0.0001	
NON-ASIAN	41	32 (78.0)	2.00 (0.62, 4.44)	41	35 (85.4)	0.23 (0.10, 0.56)	0.447 (0.271, 0.737) 0.0013	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 3 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.5018
J/K/T	91	70 (76.9)	2.66 (1.58, 4.24)	85	78 (91.8)	0.16 (0.13, 0.26)	0.346 (0.247, 0.485) <0.0001	
REST OF ASIA	25	20 (80.0)	2.23 (0.46, 3.84)	19	19 (100.0)	0.10 (0.07, 0.62)	0.329 (0.167, 0.648) 0.0008	
REST OF WORLD	42	33 (78.6)	2.00 (0.62, 4.44)	41	35 (85.4)	0.23 (0.10, 0.56)	0.455 (0.278, 0.746) 0.0015	
REGION								0.3276
ASIA	116	90 (77.6)	2.23 (1.41, 3.58)	104	97 (93.3)	0.16 (0.10, 0.23)	0.342 (0.253, 0.462) <0.0001	
NON-ASIA	42	33 (78.6)	2.00 (0.62, 4.44)	41	35 (85.4)	0.23 (0.10, 0.56)	0.455 (0.278, 0.746) 0.0015	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 4 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.4385
0	71	58 (81.7)	2.73 (1.61, 4.24)	69	65 (94.2)	0.16 (0.10, 0.23)	0.333 (0.229, 0.483) <0.0001	
1	87	65 (74.7)	1.77 (0.95, 3.84)	74	65 (87.8)	0.20 (0.10, 0.39)	0.416 (0.291, 0.594) <0.0001	
WEIGHT								0.7501
< 60 KG	96	75 (78.1)	2.56 (1.41, 4.24)	76	68 (89.5)	0.21 (0.10, 0.30)	0.394 (0.280, 0.553) <0.0001	
>= 60 KG	62	48 (77.4)	1.81 (0.62, 3.71)	69	64 (92.8)	0.16 (0.10, 0.26)	0.338 (0.226, 0.506) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 5 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.1356
STAGE I	5	4 (80.0)	12.42 (0.49, N.A.)	5	4 (80.0)	0.13 (0.10, N.A.)	0.118 (0.012, 1.131) 0.0358	
STAGE II	5	2 (40.0)	N.A. (0.39, N.A.)	5	5 (100.0)	0.10 (0.03, N.A.)	0.082 (0.009, 0.741) 0.0077	
STAGE III	33	24 (72.7)	3.71 (1.81, 6.34)	46	39 (84.8)	0.20 (0.10, 0.46)	0.377 (0.223, 0.638) 0.0002	
STAGE IV	114	92 (80.7)	1.77 (0.95, 2.66)	89	84 (94.4)	0.20 (0.10, 0.26)	0.388 (0.285, 0.529) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 6 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8088
GX	11	8 (72.7)	2.20 (0.13, 6.37)	14	14 (100.0)	0.10 (0.07, 0.30)	0.242 (0.090, 0.649) 0.0029	
G1	8	7 (87.5)	1.20 (0.03, N.A.)	8	7 (87.5)	0.39 (0.07, 1.38)	0.505 (0.158, 1.612) 0.2463	
G2	58	45 (77.6)	1.87 (0.62, 3.32)	50	45 (90.0)	0.21 (0.10, 0.39)	0.410 (0.268, 0.627) <0.0001	
G3	28	20 (71.4)	3.48 (1.12, 9.99)	36	32 (88.9)	0.21 (0.10, 0.46)	0.401 (0.227, 0.709) 0.0013	
NOT OTHERWISE SPECIFIED	51	41 (80.4)	2.66 (0.99, 5.03)	37	34 (91.9)	0.20 (0.10, 0.30)	0.318 (0.194, 0.521) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 7 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.0025*
UPPER THORACIC	37	33 (89.2)	1.61 (0.72, 3.48)	25	24 (96.0)	0.13 (0.10, 0.16)	0.279 (0.156, 0.498) <0.0001	
MIDDLE THORACIC	50	39 (78.0)	2.00 (1.15, 4.80)	52	45 (86.5)	0.39 (0.20, 1.08)	0.532 (0.345, 0.822) 0.0043	
LOWER THORACIC	59	41 (69.5)	3.71 (1.08, 6.37)	60	58 (96.7)	0.11 (0.10, 0.20)	0.222 (0.141, 0.349) <0.0001	
GASTROESOPHAGEAL JUNCTION	11	9 (81.8)	0.46 (0.10, N.A.)	8	5 (62.5)	1.18 (0.07, N.A.)	0.922 (0.291, 2.921) 0.8768	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 8 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.0722
RECURRENT - LOCO-REGIONAL	8	5 (62.5)	9.66 (0.46, N.A.)	13	12 (92.3)	0.10 (0.07, 0.13)	0.151 (0.045, 0.509) 0.0010	
RECURRENT - DISTANT	25	17 (68.0)	4.93 (2.73, 10.22)	27	23 (85.2)	0.13 (0.07, 0.46)	0.237 (0.117, 0.481) <0.0001	
DE NOVO METASTATIC	107	87 (81.3)	1.77 (0.66, 2.66)	81	76 (93.8)	0.20 (0.10, 0.26)	0.403 (0.293, 0.555) <0.0001	
UNRESECTABLE ADVANCED	18	14 (77.8)	2.69 (1.12, 11.53)	24	21 (87.5)	0.51 (0.20, 2.37)	0.506 (0.255, 1.006) 0.0482	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 9 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6552
CURRENT/FORMER	136	105 (77.2)	2.56 (1.64, 3.71)	111	101 (91.0)	0.20 (0.13, 0.23)	0.371 (0.279, 0.492) <0.0001	
NEVER/UNKNOWN	22	18 (81.8)	0.62 (0.33, 4.80)	34	31 (91.2)	0.28 (0.10, 0.49)	0.449 (0.245, 0.824) 0.0084	
ALCOHOL USE								0.8714
CURRENT/FORMER	126	99 (78.6)	2.00 (1.38, 3.45)	117	107 (91.5)	0.20 (0.13, 0.23)	0.368 (0.277, 0.489) <0.0001	
NEVER/UNKNOWN	32	24 (75.0)	3.71 (0.62, 5.52)	28	25 (89.3)	0.11 (0.07, 0.99)	0.378 (0.209, 0.684) 0.0011	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 10 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.0970
<= 1	80	66 (82.5)	2.73 (1.38, 4.24)	69	62 (89.9)	0.20 (0.13, 0.43)	0.447 (0.312, 0.640) <0.0001	
>= 2	78	57 (73.1)	1.81 (1.12, 3.71)	76	70 (92.1)	0.13 (0.10, 0.23)	0.313 (0.217, 0.451) <0.0001	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2228
< 1 YEAR	128	104 (81.3)	1.87 (1.12, 3.38)	115	106 (92.2)	0.23 (0.13, 0.30)	0.421 (0.318, 0.556) <0.0001	
1 - < 3 YEARS	25	16 (64.0)	3.71 (1.31, 10.81)	21	18 (85.7)	0.13 (0.07, 0.30)	0.284 (0.139, 0.580) 0.0003	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 11 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0518
YES	38	29 (76.3)	3.71 (1.31, 4.93)	37	33 (89.2)	0.10 (0.10, 0.13)	0.249 (0.142, 0.437) <0.0001	
NO	120	94 (78.3)	1.87 (1.28, 3.38)	108	99 (91.7)	0.23 (0.16, 0.30)	0.422 (0.316, 0.564) <0.0001	
PRIOR RADIOTHERAPY								0.2517
YES	26	17 (65.4)	3.71 (1.35, 10.81)	27	23 (85.2)	0.13 (0.07, 0.30)	0.311 (0.159, 0.606) 0.0004	
NO	132	106 (80.3)	1.94 (1.28, 3.45)	118	109 (92.4)	0.20 (0.13, 0.26)	0.394 (0.299, 0.520) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 12 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.3980
< 10	53	42 (79.2)	1.74 (0.95, 3.71)	54	49 (90.7)	0.25 (0.13, 0.95)	0.425 (0.277, 0.653) <0.0001	
>= 10	92	70 (76.1)	2.73 (1.77, 4.24)	89	81 (91.0)	0.16 (0.10, 0.23)	0.353 (0.253, 0.493) <0.0001	
PD-L1 CPS II								0.3617
< 5	29	25 (86.2)	0.95 (0.46, 1.81)	24	22 (91.7)	0.15 (0.07, 0.43)	0.497 (0.278, 0.888) 0.0187	
>= 5	116	87 (75.0)	3.45 (1.87, 4.67)	119	108 (90.8)	0.20 (0.13, 0.26)	0.345 (0.257, 0.465) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 13 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.4753
< 10%	55	42 (76.4)	2.73 (1.58, 4.44)	57	52 (91.2)	0.20 (0.10, 0.49)	0.339 (0.220, 0.521) <0.0001	
>= 10%	103	81 (78.6)	1.94 (1.12, 3.45)	88	80 (90.9)	0.18 (0.13, 0.23)	0.400 (0.291, 0.550) <0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7042
< 5%	38	32 (84.2)	1.81 (0.62, 3.71)	41	38 (92.7)	0.16 (0.07, 0.56)	0.410 (0.252, 0.668) 0.0003	
>= 5%	120	91 (75.8)	2.56 (1.35, 4.24)	104	94 (90.4)	0.20 (0.13, 0.26)	0.364 (0.269, 0.491) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 14 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	50 (31.6)	N.A. (12.98, N.A.)	145	68 (46.9)	5.85 (3.38, N.A.)	0.501 (0.346, 0.726) 0.0002	
AGE								0.8736
< 65	95	26 (27.4)	N.A. (12.98, N.A.)	75	31 (41.3)	N.A. (3.94, N.A.)	0.534 (0.316, 0.901) 0.0171	
>= 65 AND < 75	55	21 (38.2)	20.27 (4.93, N.A.)	58	30 (51.7)	4.63 (1.64, N.A.)	0.507 (0.284, 0.902) 0.0199	
>= 75	8	3 (37.5)	N.A. (0.33, N.A.)	12	7 (58.3)	2.27 (0.13, N.A.)	0.407 (0.103, 1.599) 0.1862	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 15 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2669
MALE	131	40 (30.5)	N.A. (12.98, N.A.)	122	59 (48.4)	5.16 (3.06, N.A.)	0.460 (0.307, 0.691) 0.0001	
FEMALE	27	10 (37.0)	20.27 (5.59, N.A.)	23	9 (39.1)	N.A. (2.14, N.A.)	0.749 (0.297, 1.891) 0.5425	
RACE								0.8303
ASIAN	117	43 (36.8)	20.27 (8.57, N.A.)	104	54 (51.9)	4.40 (2.14, N.A.)	0.475 (0.315, 0.716) 0.0003	
NON-ASIAN	41	7 (17.1)	N.A.	41	14 (34.1)	N.A. (3.94, N.A.)	0.458 (0.184, 1.135) 0.0843	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 16 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.8101
J/K/T	91	36 (39.6)	13.01 (5.88, N.A.)	85	48 (56.5)	3.38 (1.94, N.A.)	0.467 (0.300, 0.726) 0.0006	
REST OF ASIA	25	7 (28.0)	12.98 (5.91, N.A.)	19	6 (31.6)	N.A. (2.37, N.A.)	0.628 (0.201, 1.961) 0.4189	
REST OF WORLD	42	7 (16.7)	N.A.	41	14 (34.1)	N.A. (3.94, N.A.)	0.444 (0.179, 1.100) 0.0722	
REGION								0.7611
ASIA	116	43 (37.1)	13.01 (8.57, N.A.)	104	54 (51.9)	4.40 (2.14, N.A.)	0.481 (0.319, 0.725) 0.0004	
NON-ASIA	42	7 (16.7)	N.A.	41	14 (34.1)	N.A. (3.94, N.A.)	0.444 (0.179, 1.100) 0.0722	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 17 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.5577
0	71	32 (45.1)	11.86 (5.88, N.A.)	69	39 (56.5)	3.06 (1.64, N.A.)	0.511 (0.318, 0.822) 0.0051	
1	87	18 (20.7)	N.A.	74	29 (39.2)	N.A. (4.63, N.A.)	0.442 (0.245, 0.799) 0.0056	
WEIGHT								0.2743
< 60 KG	96	33 (34.4)	N.A. (6.08, N.A.)	76	34 (44.7)	6.90 (3.25, N.A.)	0.583 (0.359, 0.946) 0.0278	
>= 60 KG	62	17 (27.4)	N.A. (11.86, N.A.)	69	34 (49.3)	5.85 (2.04, N.A.)	0.398 (0.220, 0.720) 0.0017	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 18 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.3728
STAGE I	5	1 (20.0)	N.A. (12.98, N.A.)	5	4 (80.0)	0.13 (0.13, N.A.)	<0.001 (<0.001, N.A.) 0.0126	
STAGE II	5	0	N.E.	5	2 (40.0)	4.67 (0.10, N.A.)	N.E. 0.0715	
STAGE III	33	10 (30.3)	N.A. (5.59, N.A.)	46	19 (41.3)	N.A. (3.38, N.A.)	0.577 (0.267, 1.248) 0.1602	
STAGE IV	114	38 (33.3)	N.A. (11.53, N.A.)	89	43 (48.3)	6.90 (2.73, N.A.)	0.541 (0.347, 0.842) 0.0059	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 19 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9415
GX	11	3 (27.3)	N.A. (1.74, N.A.)	14	8 (57.1)	2.79 (0.13, N.A.)	0.374 (0.098, 1.420) 0.1350	
G1	8	4 (50.0)	12.98 (0.66, N.A.)	8	6 (75.0)	1.51 (0.10, N.A.)	0.368 (0.091, 1.480) 0.1428	
G2	58	15 (25.9)	N.A.	50	19 (38.0)	N.A. (2.79, N.A.)	0.573 (0.291, 1.129) 0.1050	
G3	28	8 (28.6)	N.A. (5.91, N.A.)	36	16 (44.4)	6.90 (3.38, N.A.)	0.555 (0.236, 1.308) 0.1718	
NOT OTHERWISE SPECIFIED	51	19 (37.3)	11.86 (5.59, N.A.)	37	19 (51.4)	5.85 (0.99, N.A.)	0.450 (0.233, 0.866) 0.0149	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 20 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.0701
UPPER THORACIC	37	13 (35.1)	13.01 (5.06, N.A.)	25	17 (68.0)	1.38 (0.16, 3.52)	0.249 (0.117, 0.530) 0.0001	
MIDDLE THORACIC	50	18 (36.0)	11.86 (4.93, N.A.)	52	18 (34.6)	N.A. (4.67, N.A.)	1.007 (0.523, 1.936) 0.9787	
LOWER THORACIC	59	18 (30.5)	N.A. (11.53, N.A.)	60	30 (50.0)	5.16 (2.14, N.A.)	0.405 (0.220, 0.744) 0.0027	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	3 (37.5)	N.A. (0.13, N.A.)	N.E. 0.0244	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 21 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.4604
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	6 (46.2)	N.A. (0.13, N.A.)	N.E. 0.0265	
RECURRENT - DISTANT	25	7 (28.0)	12.98 (5.59, N.A.)	27	15 (55.6)	4.52 (0.13, N.A.)	0.240 (0.090, 0.637) 0.0022	
DE NOVO METASTATIC	107	37 (34.6)	N.A. (11.86, N.A.)	81	38 (46.9)	6.90 (2.79, N.A.)	0.602 (0.380, 0.952) 0.0293	
UNRESECTABLE ADVANCED	18	6 (33.3)	N.A. (3.48, N.A.)	24	9 (37.5)	N.A. (2.27, N.A.)	0.679 (0.239, 1.924) 0.4623	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 22 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.7295
CURRENT/FORMER	136	44 (32.4)	N.A. (12.98, N.A.)	111	52 (46.8)	5.85 (3.52, N.A.)	0.513 (0.341, 0.772) 0.0012	
NEVER/UNKNOWN	22	6 (27.3)	N.A. (5.59, N.A.)	34	16 (47.1)	N.A. (0.99, N.A.)	0.428 (0.167, 1.100) 0.0701	
ALCOHOL USE								0.7567
CURRENT/FORMER	126	41 (32.5)	N.A. (11.86, N.A.)	117	57 (48.7)	5.16 (3.06, N.A.)	0.488 (0.324, 0.733) 0.0005	
NEVER/UNKNOWN	32	9 (28.1)	N.A. (6.08, N.A.)	28	11 (39.3)	N.A. (1.64, N.A.)	0.584 (0.241, 1.415) 0.2333	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 23 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9180
<= 1	80	28 (35.0)	20.27 (11.53, N.A.)	69	36 (52.2)	4.40 (2.14, N.A.)	0.472 (0.286, 0.779) 0.0028	
>= 2	78	22 (28.2)	N.A. (13.01, N.A.)	76	32 (42.1)	N.A. (3.25, N.A.)	0.520 (0.300, 0.902) 0.0185	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.1628
< 1 YEAR	128	45 (35.2)	20.27 (11.53, N.A.)	115	52 (45.2)	6.90 (3.38, N.A.)	0.613 (0.409, 0.918) 0.0172	
1 - < 3 YEARS	25	4 (16.0)	N.A.	21	9 (42.9)	4.67 (2.14, N.A.)	0.246 (0.075, 0.810) 0.0130	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 24 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0074*
YES	38	8 (21.1)	N.A. (12.98, N.A.)	37	21 (56.8)	4.40 (0.16, N.A.)	0.187 (0.080, 0.438) <0.0001	
NO	120	42 (35.0)	20.27 (11.53, N.A.)	108	47 (43.5)	N.A. (3.52, N.A.)	0.672 (0.441, 1.024) 0.0643	
PRIOR RADIOTHERAPY								0.6350
YES	26	6 (23.1)	N.A. (5.59, N.A.)	27	11 (40.7)	N.A. (0.72, N.A.)	0.409 (0.150, 1.115) 0.0729	
NO	132	44 (33.3)	N.A. (11.86, N.A.)	118	57 (48.3)	5.85 (2.79, N.A.)	0.512 (0.343, 0.764) 0.0009	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 25 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9540
< 10	53	17 (32.1)	N.A. (5.52, N.A.)	54	24 (44.4)	5.16 (3.06, N.A.)	0.560 (0.299, 1.047) 0.0664	
>= 10	92	31 (33.7)	20.27 (11.53, N.A.)	89	42 (47.2)	6.90 (2.27, N.A.)	0.531 (0.332, 0.850) 0.0080	
PD-L1 CPS II								0.7767
< 5	29	9 (31.0)	N.A. (2.73, N.A.)	24	10 (41.7)	4.40 (0.99, N.A.)	0.674 (0.273, 1.660) 0.3877	
>= 5	116	39 (33.6)	20.27 (11.53, N.A.)	119	56 (47.1)	5.85 (3.06, N.A.)	0.523 (0.346, 0.792) 0.0020	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 26 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5693
< 10%	55	15 (27.3)	N.A. (3.94, N.A.)	57	21 (36.8)	N.A. (1.94, N.A.)	0.608 (0.312, 1.183) 0.1414	
>= 10%	103	35 (34.0)	20.27 (11.53, N.A.)	88	47 (53.4)	4.63 (2.37, N.A.)	0.443 (0.283, 0.692) 0.0003	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.6203
< 5%	38	12 (31.6)	N.A. (6.08, N.A.)	41	17 (41.5)	N.A. (2.79, N.A.)	0.604 (0.288, 1.270) 0.1840	
>= 5%	120	38 (31.7)	N.A. (11.86, N.A.)	104	51 (49.0)	5.16 (2.37, N.A.)	0.462 (0.301, 0.710) 0.0003	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 27 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	48 (30.4)	N.A. (9.69, N.A.)	145	25 (17.2)	N.A. (15.28, N.A.)	1.757 (1.082, 2.854) 0.0209	
AGE								0.3332
< 65	95	27 (28.4)	N.A. (7.10, N.A.)	75	12 (16.0)	N.A. (15.28, N.A.)	1.909 (0.965, 3.775) 0.0585	
>= 65 AND < 75	55	16 (29.1)	N.A. (6.51, N.A.)	58	12 (20.7)	N.A. (7.85, N.A.)	1.274 (0.600, 2.702) 0.5259	
>= 75	8	5 (62.5)	7.54 (0.56, N.A.)	12	1 (8.3)	N.A.	5.967 (0.686, 51.883) 0.0673	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 28 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1669
MALE	131	41 (31.3)	11.60 (8.87, N.A.)	122	19 (15.6)	N.A. (15.28, N.A.)	2.057 (1.191, 3.552) 0.0082	
FEMALE	27	7 (25.9)	N.A. (6.51, N.A.)	23	6 (26.1)	N.A.	0.893 (0.300, 2.661) 0.8395	
RACE								0.2226
ASIAN	117	34 (29.1)	N.A. (9.69, N.A.)	104	14 (13.5)	N.A. (15.28, N.A.)	2.178 (1.166, 4.069) 0.0123	
NON-ASIAN	41	14 (34.1)	N.A. (5.42, N.A.)	41	11 (26.8)	N.A.	1.233 (0.559, 2.716) 0.6066	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 29 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.3551
J/K/T	91	27 (29.7)	N.A. (8.87, N.A.)	85	11 (12.9)	N.A. (15.28, N.A.)	2.468 (1.220, 4.993) 0.0093	
REST OF ASIA	25	6 (24.0)	N.A. (9.69, N.A.)	19	3 (15.8)	N.A.	1.192 (0.292, 4.863) 0.8067	
REST OF WORLD	42	15 (35.7)	10.02 (5.55, N.A.)	41	11 (26.8)	N.A.	1.239 (0.568, 2.704) 0.5921	
REGION								0.2545
ASIA	116	33 (28.4)	N.A. (9.69, N.A.)	104	14 (13.5)	N.A. (15.28, N.A.)	2.155 (1.150, 4.038) 0.0139	
NON-ASIA	42	15 (35.7)	10.02 (5.55, N.A.)	41	11 (26.8)	N.A.	1.239 (0.568, 2.704) 0.5921	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 30 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.3562
0	71	25 (35.2)	11.60 (6.51, N.A.)	69	10 (14.5)	N.A. (15.28, N.A.)	2.400 (1.152, 5.002) 0.0158	
1	87	23 (26.4)	N.A. (10.02, N.A.)	74	13 (17.6)	N.A.	1.561 (0.789, 3.089) 0.1968	
WEIGHT								0.1856
< 60 KG	96	28 (29.2)	N.A. (10.02, N.A.)	76	16 (21.1)	15.28 (15.28, N.A.)	1.307 (0.705, 2.424) 0.3921	
>= 60 KG	62	20 (32.3)	9.69 (5.62, N.A.)	69	9 (13.0)	N.A.	2.622 (1.192, 5.769) 0.0128	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 31 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (1) (mon)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (1) (mon)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9152
STAGE I	5	1 (20.0)	N.A. (1.97, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	2 (40.0)	N.A. (1.41, N.A.)	5	0	N.E.	N.E. 0.2457	
STAGE III	33	10 (30.3)	11.60 (6.34, N.A.)	46	10 (21.7)	N.A. (15.28, N.A.)	1.180 (0.488, 2.857) 0.7128	
STAGE IV	114	35 (30.7)	N.A. (6.51, N.A.)	89	15 (16.9)	N.A.	1.937 (1.056, 3.552) 0.0295	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 32 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9574
GX	11	1 (9.1)	N.A. (0.56, N.A.)	14	0	N.E.	N.E. 0.2367	
G1	8	3 (37.5)	10.22 (0.03, N.A.)	8	3 (37.5)	N.A. (0.62, N.A.)	0.732 (0.122, 4.386) 0.7316	
G2	58	18 (31.0)	N.A. (5.55, N.A.)	50	9 (18.0)	N.A. (15.28, N.A.)	1.691 (0.759, 3.771) 0.1946	
G3	28	8 (28.6)	N.A. (5.42, N.A.)	36	6 (16.7)	N.A.	1.696 (0.587, 4.905) 0.3240	
NOT OTHERWISE SPECIFIED	51	17 (33.3)	9.69 (6.34, N.A.)	37	7 (18.9)	N.A. (7.85, N.A.)	1.627 (0.672, 3.939) 0.2737	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 33 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.1267
UPPER THORACIC	37	16 (43.2)	7.10 (4.24, N.A.)	25	1 (4.0)	N.A.	14.281 (1.892,>99.999) 0.0007	
MIDDLE THORACIC	50	13 (26.0)	9.69 (5.78, N.A.)	52	9 (17.3)	15.28 (15.28, N.A.)	1.587 (0.678, 3.716) 0.2830	
LOWER THORACIC	59	15 (25.4)	N.A. (10.22, N.A.)	60	13 (21.7)	N.A.	1.071 (0.508, 2.258) 0.8519	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	N.A. (1.87, N.A.)	8	2 (25.0)	N.A. (0.30, N.A.)	0.694 (0.098, 4.929) 0.7131	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 34 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3972
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	7.10 (0.46, N.A.)	13	3 (23.1)	N.A. (1.68, N.A.)	1.156 (0.190, 7.018) 0.8749	
RECURRENT - DISTANT	25	8 (32.0)	11.60 (5.62, N.A.)	27	1 (3.7)	N.A.	7.138 (0.871, 58.479) 0.0330	
DE NOVO METASTATIC	107	32 (29.9)	N.A. (6.51, N.A.)	81	15 (18.5)	N.A.	1.701 (0.920, 3.146) 0.0864	
UNRESECTABLE ADVANCED	18	6 (33.3)	N.A. (5.42, N.A.)	24	6 (25.0)	15.28 (15.28, N.A.)	1.121 (0.359, 3.496) 0.8442	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 35 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.4011
CURRENT/FORMER	136	45 (33.1)	11.60 (6.51, N.A.)	111	20 (18.0)	N.A. (15.28, N.A.)	1.816 (1.070, 3.081) 0.0247	
NEVER/UNKNOWN	22	3 (13.6)	N.A.	34	5 (14.7)	N.A.	1.046 (0.250, 4.379) 0.9526	
ALCOHOL USE								0.7576
CURRENT/FORMER	126	43 (34.1)	10.22 (6.51, N.A.)	117	22 (18.8)	N.A. (15.28, N.A.)	1.808 (1.080, 3.026) 0.0221	
NEVER/UNKNOWN	32	5 (15.6)	N.A.	28	3 (10.7)	N.A.	1.678 (0.401, 7.032) 0.4738	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 36 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4510
<= 1	80	26 (32.5)	N.A. (8.87, N.A.)	69	15 (21.7)	N.A. (15.28, N.A.)	1.462 (0.774, 2.765) 0.2386	
>= 2	78	22 (28.2)	N.A. (6.51, N.A.)	76	10 (13.2)	N.A.	2.228 (1.052, 4.718) 0.0315	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9430
< 1 YEAR	128	41 (32.0)	N.A. (6.51, N.A.)	115	22 (19.1)	N.A. (15.28, N.A.)	1.685 (1.002, 2.835) 0.0467	
1 - < 3 YEARS	25	6 (24.0)	10.22 (7.10, N.A.)	21	3 (14.3)	N.A.	1.493 (0.372, 5.997) 0.5695	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 37 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0727
YES	38	14 (36.8)	10.22 (5.62, N.A.)	37	3 (8.1)	N.A. (15.28, N.A.)	4.815 (1.383, 16.767) 0.0063	
NO	120	34 (28.3)	N.A. (8.87, N.A.)	108	22 (20.4)	N.A. (15.28, N.A.)	1.368 (0.798, 2.344) 0.2514	
PRIOR RADIOTHERAPY								0.8053
YES	26	6 (23.1)	11.60 (7.10, N.A.)	27	3 (11.1)	N.A. (15.28, N.A.)	1.984 (0.493, 7.988) 0.3260	
NO	132	42 (31.8)	N.A. (8.87, N.A.)	118	22 (18.6)	N.A. (15.28, N.A.)	1.697 (1.011, 2.848) 0.0428	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 38 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.8179
< 10	53	15 (28.3)	N.A. (6.34, N.A.)	54	8 (14.8)	15.28 (15.28, N.A.)	1.858 (0.784, 4.406) 0.1528	
>= 10	92	29 (31.5)	N.A. (8.87, N.A.)	89	17 (19.1)	N.A.	1.656 (0.909, 3.016) 0.0957	
PD-L1 CPS II								0.9076
< 5	29	6 (20.7)	N.A. (4.44, N.A.)	24	3 (12.5)	N.A.	1.757 (0.439, 7.036) 0.4196	
>= 5	116	38 (32.8)	11.60 (7.10, N.A.)	119	22 (18.5)	N.A. (15.28, N.A.)	1.737 (1.026, 2.940) 0.0375	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 39 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9169
< 10%	55	18 (32.7)	11.60 (5.62, N.A.)	57	10 (17.5)	N.A.	1.716 (0.790, 3.731) 0.1667	
>= 10%	103	30 (29.1)	N.A. (8.87, N.A.)	88	15 (17.0)	15.28 (15.28, N.A.)	1.779 (0.955, 3.314) 0.0659	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.6798
< 5%	38	15 (39.5)	6.51 (4.44, N.A.)	41	8 (19.5)	N.A.	2.093 (0.884, 4.956) 0.0849	
>= 5%	120	33 (27.5)	N.A. (10.22, N.A.)	104	17 (16.3)	15.28 (15.28, N.A.)	1.659 (0.921, 2.989) 0.0882	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 40 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	46 (29.1)	N.A. (13.60, N.A.)	145	84 (57.9)	2.17 (1.02, 5.45)	0.331 (0.230, 0.476) <0.0001	
AGE								0.5563
< 65	95	31 (32.6)	N.A. (7.62, N.A.)	75	45 (60.0)	3.52 (0.23, 5.72)	0.365 (0.230, 0.580) <0.0001	
>= 65 AND < 75	55	14 (25.5)	N.A.	58	32 (55.2)	1.94 (0.20, N.A.)	0.315 (0.167, 0.592) 0.0002	
>= 75	8	1 (12.5)	N.A. (3.06, N.A.)	12	7 (58.3)	4.93 (0.07, N.A.)	0.133 (0.016, 1.097) 0.0283	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 41 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6675
MALE	131	34 (26.0)	N.A. (13.60, N.A.)	122	67 (54.9)	4.11 (1.84, 7.36)	0.320 (0.211, 0.487) <0.0001	
FEMALE	27	12 (44.4)	N.A. (2.63, N.A.)	23	17 (73.9)	0.10 (0.07, 1.02)	0.305 (0.144, 0.647) 0.0016	
RACE								0.5971
ASIAN	117	32 (27.4)	N.A.	104	60 (57.7)	2.53 (0.99, 5.72)	0.312 (0.202, 0.482) <0.0001	
NON-ASIAN	41	14 (34.1)	13.60 (5.03, N.A.)	41	24 (58.5)	1.97 (0.10, N.A.)	0.393 (0.201, 0.767) 0.0053	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 42 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.6899
J/K/T	91	23 (25.3)	N.A.	85	50 (58.8)	2.53	0.290	
						(0.95, 5.72)	(0.176, 0.476)	
							<0.0001	
REST OF ASIA	25	9 (36.0)	13.01	19	10 (52.6)	5.45	0.418	
			(4.40, N.A.)			(0.07, N.A.)	(0.164, 1.064)	
							0.0633	
REST OF WORLD	42	14 (33.3)	13.60	41	24 (58.5)	1.97	0.380	
			(5.03, N.A.)			(0.10, N.A.)	(0.195, 0.742)	
							0.0038	
REGION								0.6787
ASIA	116	32 (27.6)	N.A.	104	60 (57.7)	2.53	0.315	
			(13.01, N.A.)			(0.99, 5.72)	(0.204, 0.487)	
							<0.0001	
NON-ASIA	42	14 (33.3)	13.60	41	24 (58.5)	1.97	0.380	
			(5.03, N.A.)			(0.10, N.A.)	(0.195, 0.742)	
							0.0038	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 43 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6215
0	71	24 (33.8)	N.A. (10.81, N.A.)	69	41 (59.4)	1.84 (0.23, 7.36)	0.372 (0.224, 0.618) <0.0001	
1	87	22 (25.3)	N.A. (13.01, N.A.)	74	42 (56.8)	3.52 (0.99, 5.55)	0.296 (0.175, 0.501) <0.0001	
WEIGHT								0.6879
< 60 KG	96	26 (27.1)	N.A. (13.01, N.A.)	76	43 (56.6)	1.94 (0.23, N.A.)	0.310 (0.189, 0.508) <0.0001	
>= 60 KG	62	20 (32.3)	N.A. (7.10, N.A.)	69	41 (59.4)	3.81 (0.16, 5.72)	0.367 (0.214, 0.630) 0.0002	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 44 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9787
STAGE I	5	2 (40.0)	13.01 (0.49, N.A.)	5	3 (60.0)	2.17 (0.10, N.A.)	0.256 (0.026, 2.479) 0.2132	
STAGE II	5	1 (20.0)	N.A. (0.39, N.A.)	5	2 (40.0)	N.A. (0.03, N.A.)	0.389 (0.035, 4.337) 0.4261	
STAGE III	33	8 (24.2)	N.A. (10.81, N.A.)	46	25 (54.3)	1.97 (0.23, N.A.)	0.267 (0.118, 0.603) 0.0008	
STAGE IV	114	34 (29.8)	N.A.	89	54 (60.7)	2.53 (0.23, 5.55)	0.344 (0.223, 0.529) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 45 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8659
GX	11	4 (36.4)	N.A. (1.58, N.A.)	14	10 (71.4)	0.11 (0.10, N.A.)	0.323 (0.100, 1.041) 0.0570	
G1	8	3 (37.5)	13.01 (2.30, N.A.)	8	3 (37.5)	N.A. (0.07, N.A.)	0.598 (0.099, 3.603) 0.5706	
G2	58	20 (34.5)	N.A. (5.16, N.A.)	50	33 (66.0)	1.08 (0.10, 4.24)	0.288 (0.161, 0.517) <0.0001	
G3	28	6 (21.4)	N.A. (7.10, N.A.)	36	17 (47.2)	5.55 (0.99, N.A.)	0.358 (0.141, 0.911) 0.0259	
NOT OTHERWISE SPECIFIED	51	13 (25.5)	N.A. (10.81, N.A.)	37	21 (56.8)	1.84 (0.23, N.A.)	0.291 (0.145, 0.587) 0.0003	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 46 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.5370
UPPER THORACIC	37	13 (35.1)	10.81 (5.16, N.A.)	25	17 (68.0)	0.23 (0.13, 5.72)	0.255 (0.121, 0.537) 0.0001	
MIDDLE THORACIC	50	13 (26.0)	N.A. (7.62, N.A.)	52	26 (50.0)	4.24 (0.99, N.A.)	0.389 (0.199, 0.759) 0.0045	
LOWER THORACIC	59	15 (25.4)	N.A.	60	38 (63.3)	1.87 (0.10, 5.45)	0.256 (0.138, 0.473) <0.0001	
GASTROESOPHAGEAL JUNCTION	11	4 (36.4)	13.60 (0.66, N.A.)	8	3 (37.5)	N.A. (0.07, N.A.)	0.618 (0.124, 3.084) 0.5752	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 47 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.8650
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	7.10 (0.66, N.A.)	13	7 (53.8)	0.23 (0.07, N.A.)	0.290 (0.059, 1.423) 0.1111	
RECURRENT - DISTANT	25	7 (28.0)	13.01 (10.81, N.A.)	27	14 (51.9)	2.17 (0.10, N.A.)	0.301 (0.114, 0.796) 0.0113	
DE NOVO METASTATIC	107	34 (31.8)	N.A. (7.62, N.A.)	81	50 (61.7)	1.94 (0.23, 5.55)	0.355 (0.229, 0.550) <0.0001	
UNRESECTABLE ADVANCED	18	3 (16.7)	N.A. (13.60, N.A.)	24	13 (54.2)	4.24 (0.99, N.A.)	0.192 (0.053, 0.690) 0.0053	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 48 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.4845
CURRENT/FORMER	136	37 (27.2)	N.A. (13.60, N.A.)	111	63 (56.8)	2.53 (0.99, 5.55)	0.319 (0.211, 0.481) <0.0001	
NEVER/UNKNOWN	22	9 (40.9)	6.28 (2.46, N.A.)	34	21 (61.8)	1.08 (0.10, N.A.)	0.445 (0.202, 0.982) 0.0446	
ALCOHOL USE								0.9752
CURRENT/FORMER	126	35 (27.8)	N.A.	117	67 (57.3)	3.52 (1.05, 5.55)	0.332 (0.220, 0.502) <0.0001	
NEVER/UNKNOWN	32	11 (34.4)	13.60 (5.16, N.A.)	28	17 (60.7)	0.59 (0.07, N.A.)	0.326 (0.151, 0.704) 0.0033	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 49 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4193
<= 1	80	24 (30.0)	N.A. (13.01, N.A.)	69	39 (56.5)	4.11 (1.12, 7.36)	0.377 (0.226, 0.630) 0.0001	
>= 2	78	22 (28.2)	N.A. (7.10, N.A.)	76	45 (59.2)	1.02 (0.16, 5.72)	0.296 (0.177, 0.496) <0.0001	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.5570
< 1 YEAR	128	38 (29.7)	N.A.	115	69 (60.0)	2.53 (0.99, 5.45)	0.335 (0.224, 0.500) <0.0001	
1 - < 3 YEARS	25	7 (28.0)	10.81 (7.10, N.A.)	21	9 (42.9)	N.A. (0.13, N.A.)	0.402 (0.142, 1.138) 0.0780	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 50 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.6950
YES	38	11 (28.9)	N.A. (6.08, N.A.)	37	22 (59.5)	1.28 (0.10, N.A.)	0.299 (0.144, 0.623) 0.0007	
NO	120	35 (29.2)	N.A. (13.60, N.A.)	108	62 (57.4)	3.81 (1.02, 5.55)	0.342 (0.225, 0.522) <0.0001	
PRIOR RADIOTHERAPY								0.7838
YES	26	6 (23.1)	N.A. (7.10, N.A.)	27	11 (40.7)	N.A. (0.10, N.A.)	0.402 (0.148, 1.095) 0.0712	
NO	132	40 (30.3)	N.A. (13.60, N.A.)	118	73 (61.9)	1.97 (0.99, 4.93)	0.322 (0.218, 0.476) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 51 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.2291
< 10	53	12 (22.6)	N.A. (10.81, N.A.)	54	33 (61.1)	2.53 (0.99, 5.55)	0.226 (0.114, 0.449) <0.0001	
>= 10	92	29 (31.5)	N.A. (13.01, N.A.)	89	49 (55.1)	2.17 (0.23, N.A.)	0.394 (0.248, 0.626) <0.0001	
PD-L1 CPS II								0.6191
< 5	29	7 (24.1)	N.A. (6.08, N.A.)	24	14 (58.3)	1.48 (0.10, N.A.)	0.286 (0.115, 0.711) 0.0043	
>= 5	116	34 (29.3)	N.A. (13.01, N.A.)	119	68 (57.1)	2.53 (1.02, 5.55)	0.341 (0.225, 0.517) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 52 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.6696
< 10%	55	15 (27.3)	N.A. (10.81, N.A.)	57	32 (56.1)	3.81 (0.20, N.A.)	0.290 (0.155, 0.544) <0.0001	
>= 10%	103	31 (30.1)	N.A. (13.01, N.A.)	88	52 (59.1)	2.17 (0.95, 5.45)	0.352 (0.224, 0.551) <0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.5392
< 5%	38	9 (23.7)	N.A. (6.28, N.A.)	41	23 (56.1)	3.81 (0.13, N.A.)	0.280 (0.129, 0.608) 0.0006	
>= 5%	120	37 (30.8)	N.A. (13.01, N.A.)	104	61 (58.7)	2.17 (0.99, 5.45)	0.349 (0.231, 0.528) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 53 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	19 (12.0)	N.A.	145	34 (23.4)	N.A.	0.440 (0.250, 0.775) 0.0035	
AGE								0.1005
< 65	95	12 (12.6)	N.A.	75	12 (16.0)	N.A.	0.739 (0.331, 1.650) 0.4603	
>= 65 AND < 75	55	4 (7.3)	N.A.	58	18 (31.0)	N.A.	0.197 (0.067, 0.583) 0.0011	
>= 75	8	3 (37.5)	11.04 (3.25, N.A.)	12	4 (33.3)	N.A. (0.26, N.A.)	0.726 (0.156, 3.381) 0.6826	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 54 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8289
MALE	131	15 (11.5)	N.A.	122	28 (23.0)	N.A.	0.421 (0.224, 0.792) 0.0058	
FEMALE	27	4 (14.8)	N.A.	23	6 (26.1)	N.A.	0.514 (0.145, 1.824) 0.2945	
RACE								0.1015
ASIAN	117	18 (15.4)	N.A.	104	25 (24.0)	N.A.	0.565 (0.308, 1.037) 0.0624	
NON-ASIAN	41	1 (2.4)	N.A. (12.94, N.A.)	41	9 (22.0)	N.A.	0.079 (0.010, 0.654) 0.0034	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 55 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.2358
J/K/T	91	16 (17.6)	N.A.	85	23 (27.1)	N.A.	0.577 (0.304, 1.093) 0.0887	
REST OF ASIA	25	2 (8.0)	N.A.	19	2 (10.5)	N.A.	0.679 (0.096, 4.831) 0.6975	
REST OF WORLD	42	1 (2.4)	N.A. (12.94, N.A.)	41	9 (22.0)	N.A.	0.078 (0.009, 0.640) 0.0030	
REGION								0.0941
ASIA	116	18 (15.5)	N.A.	104	25 (24.0)	N.A.	0.571 (0.311, 1.049) 0.0678	
NON-ASIA	42	1 (2.4)	N.A. (12.94, N.A.)	41	9 (22.0)	N.A.	0.078 (0.009, 0.640) 0.0030	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 56 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.8177
0	71	11 (15.5)	N.A.	69	19 (27.5)	N.A.	0.456 (0.216, 0.961) 0.0345	
1	87	8 (9.2)	N.A.	74	15 (20.3)	N.A.	0.402 (0.169, 0.958) 0.0336	
WEIGHT								0.4505
< 60 KG	96	12 (12.5)	N.A.	76	22 (28.9)	N.A.	0.370 (0.183, 0.748) 0.0040	
>= 60 KG	62	7 (11.3)	N.A.	69	12 (17.4)	N.A.	0.566 (0.219, 1.458) 0.2338	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 57 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.4980
STAGE I	5	1 (20.0)	N.A. (1.51, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	0	N.E.	5	2 (40.0)	N.A. (0.26, N.A.)	N.E. 0.1343	
STAGE III	33	1 (3.0)	N.A.	46	11 (23.9)	N.A.	0.114 (0.015, 0.882) 0.0119	
STAGE IV	114	17 (14.9)	N.A.	89	21 (23.6)	N.A.	0.547 (0.287, 1.042) 0.0635	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 58 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.5591
GX	11	2 (18.2)	N.A. (0.95, N.A.)	14	4 (28.6)	N.A. (1.35, N.A.)	0.654 (0.120, 3.575) 0.6294	
G1	8	1 (12.5)	N.A. (5.26, N.A.)	8	3 (37.5)	N.A. (0.26, N.A.)	0.270 (0.028, 2.604) 0.2245	
G2	58	6 (10.3)	N.A.	50	9 (18.0)	N.A.	0.502 (0.178, 1.416) 0.1854	
G3	28	1 (3.6)	N.A. (12.94, N.A.)	36	10 (27.8)	N.A.	0.088 (0.011, 0.722) 0.0058	
NOT OTHERWISE SPECIFIED	51	8 (15.7)	N.A.	37	8 (21.6)	N.A. (6.08, N.A.)	0.672 (0.252, 1.794) 0.4266	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 59 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.3472
UPPER THORACIC	37	5 (13.5)	N.A.	25	8 (32.0)	N.A.	0.328	
						(2.83, N.A.)	(0.106, 1.010)	
							0.0415	
MIDDLE THORACIC	50	8 (16.0)	N.A.	52	9 (17.3)	N.A.	0.890	
			(11.04, N.A.)				(0.343, 2.312)	
							0.8148	
LOWER THORACIC	59	5 (8.5)	N.A.	60	15 (25.0)	N.A.	0.304	
							(0.111, 0.838)	
							0.0148	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A.	8	2 (25.0)	N.A.	0.309	
						(0.26, N.A.)	(0.028, 3.422)	
							0.3113	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 60 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5469
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	4 (30.8)	N.A. (0.95, N.A.)	N.E. 0.0628	
RECURRENT - DISTANT	25	2 (8.0)	N.A.	27	10 (37.0)	N.A. (1.35, N.A.)	0.171 (0.037, 0.783) 0.0099	
DE NOVO METASTATIC	107	17 (15.9)	N.A.	81	20 (24.7)	N.A.	0.546 (0.284, 1.049) 0.0664	
UNRESECTABLE ADVANCED	18	0	N.E.	24	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 61 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6221
CURRENT/FORMER	136	16 (11.8)	N.A.	111	27 (24.3)	N.A.	0.404 (0.216, 0.754) 0.0033	
NEVER/UNKNOWN	22	3 (13.6)	N.A.	34	7 (20.6)	N.A.	0.626 (0.162, 2.423) 0.4921	
ALCOHOL USE								0.4657
CURRENT/FORMER	126	18 (14.3)	N.A.	117	30 (25.6)	N.A.	0.465 (0.258, 0.839) 0.0094	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	4 (14.3)	N.A.	0.211 (0.024, 1.888) 0.1254	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 62 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4878
<= 1	80	10 (12.5)	N.A.	69	14 (20.3)	N.A.	0.550 (0.244, 1.241) 0.1451	
>= 2	78	9 (11.5)	N.A.	76	20 (26.3)	N.A.	0.362 (0.163, 0.805) 0.0095	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9862
< 1 YEAR	128	19 (14.8)	N.A.	115	24 (20.9)	N.A.	0.626 (0.341, 1.147) 0.1275	
1 - < 3 YEARS	25	0	N.E.	21	7 (33.3)	N.A. (1.35, N.A.)	N.E. 0.0014	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 63 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0419*
YES	38	3 (7.9)	N.A. (2.83, N.A.)	37	14 (37.8)	N.A. (2.83, N.A.)	0.153 (0.044, 0.534) 0.0007	
NO	120	16 (13.3)	N.A.	108	20 (18.5)	N.A.	0.640 (0.330, 1.241) 0.1844	
PRIOR RADIOTHERAPY								0.1355
YES	26	2 (7.7)	N.A. (0.95, N.A.)	27	10 (37.0)	N.A. (0.95, N.A.)	0.170 (0.037, 0.779) 0.0094	
NO	132	17 (12.9)	N.A.	118	24 (20.3)	N.A.	0.554 (0.296, 1.035) 0.0608	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 64 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.1132
< 10	53	8 (15.1)	N.A. (11.04, N.A.)	54	9 (16.7)	N.A.	0.803 (0.309, 2.091) 0.6533	
>= 10	92	10 (10.9)	N.A.	89	25 (28.1)	N.A.	0.325 (0.155, 0.681) 0.0018	
PD-L1 CPS II								0.2018
< 5	29	5 (17.2)	N.A. (11.04, N.A.)	24	4 (16.7)	N.A.	0.841 (0.210, 3.365) 0.8062	
>= 5	116	13 (11.2)	N.A.	119	30 (25.2)	N.A.	0.382 (0.199, 0.735) 0.0028	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 65 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Stomatitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.8856
< 10%	55	7 (12.7)	N.A.	57	13 (22.8)	N.A.	0.439 (0.173, 1.113) 0.0749	
>= 10%	103	12 (11.7)	N.A.	88	21 (23.9)	N.A.	0.433 (0.212, 0.884) 0.0184	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9437
< 5%	38	6 (15.8)	N.A. (11.04, N.A.)	41	12 (29.3)	N.A.	0.399 (0.148, 1.073) 0.0603	
>= 5%	120	13 (10.8)	N.A.	104	22 (21.2)	N.A.	0.459 (0.230, 0.915) 0.0238	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 66 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	94 (59.5)	3.98 (2.66, 6.37)	145	99 (68.3)	1.97 (1.12, 2.92)	0.658 (0.494, 0.877) 0.0044	
AGE								0.1104
< 65	95	56 (58.9)	3.06 (2.27, 8.84)	75	52 (69.3)	1.97 (1.02, 3.25)	0.713 (0.488, 1.043) 0.0825	
>= 65 AND < 75	55	35 (63.6)	4.93 (1.91, 8.54)	58	37 (63.8)	2.00 (0.49, 4.80)	0.697 (0.431, 1.127) 0.1423	
>= 75	8	3 (37.5)	N.A. (0.13, N.A.)	12	10 (83.3)	1.22 (0.13, 4.30)	0.210 (0.055, 0.799) 0.0128	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 67 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2800
MALE	131	80 (61.1)	3.88 (2.30, 6.31)	122	83 (68.0)	1.97 (1.15, 3.22)	0.701 (0.512, 0.958) 0.0268	
FEMALE	27	14 (51.9)	6.37 (1.84, N.A.)	23	16 (69.6)	1.94 (0.13, 4.53)	0.475 (0.227, 0.991) 0.0431	
RACE								0.2668
ASIAN	117	74 (63.2)	3.91 (2.30, 6.14)	104	70 (67.3)	1.94 (1.02, 4.30)	0.722 (0.518, 1.007) 0.0578	
NON-ASIAN	41	20 (48.8)	6.37 (2.04, N.A.)	41	29 (70.7)	2.07 (0.30, 3.81)	0.511 (0.285, 0.915) 0.0215	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 68 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.1273
J/K/T	91	56 (61.5)	3.94 (2.14, 8.84)	85	61 (71.8)	1.91 (0.99, 3.22)	0.629 (0.434, 0.912) 0.0145	
REST OF ASIA	25	17 (68.0)	2.69 (0.72, 6.47)	19	9 (47.4)	4.53 (0.10, N.A.)	1.286 (0.567, 2.917) 0.5390	
REST OF WORLD	42	21 (50.0)	8.54 (2.04, N.A.)	41	29 (70.7)	2.07 (0.30, 3.81)	0.506 (0.284, 0.900) 0.0184	
REGION								0.2811
ASIA	116	73 (62.9)	3.88 (2.27, 6.14)	104	70 (67.3)	1.94 (1.02, 4.30)	0.724 (0.519, 1.011) 0.0611	
NON-ASIA	42	21 (50.0)	8.54 (2.04, N.A.)	41	29 (70.7)	2.07 (0.30, 3.81)	0.506 (0.284, 0.900) 0.0184	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 69 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7859
0	71	44 (62.0)	3.91 (2.14, 12.39)	69	48 (69.6)	1.91 (0.99, 2.83)	0.636 (0.419, 0.965) 0.0339	
1	87	50 (57.5)	4.57 (2.27, 8.84)	74	49 (66.2)	2.10 (0.36, 4.47)	0.690 (0.462, 1.031) 0.0713	
WEIGHT								0.8836
< 60 KG	96	56 (58.3)	3.98 (2.33, 8.54)	76	51 (67.1)	2.04 (0.62, 4.63)	0.690 (0.470, 1.013) 0.0593	
>= 60 KG	62	38 (61.3)	3.71 (2.04, 12.39)	69	48 (69.6)	1.91 (0.99, 3.22)	0.622 (0.399, 0.969) 0.0355	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 70 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.0985
STAGE I	5	3 (60.0)	3.98 (1.87, N.A.)	5	5 (100.0)	0.99 (0.20, N.A.)	0.281 (0.063, 1.244) 0.0781	
STAGE II	5	3 (60.0)	2.33 (1.18, N.A.)	5	2 (40.0)	N.A. (0.03, N.A.)	1.399 (0.229, 8.547) 0.7147	
STAGE III	33	14 (42.4)	6.47 (3.06, N.A.)	46	32 (69.6)	0.99 (0.20, 2.00)	0.401 (0.213, 0.755) 0.0037	
STAGE IV	114	73 (64.0)	3.88 (1.91, 6.31)	89	60 (67.4)	2.53 (1.74, 4.47)	0.775 (0.547, 1.099) 0.1560	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 71 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.1791
GX	11	7 (63.6)	6.37 (0.13, N.A.)	14	12 (85.7)	1.10 (0.07, 2.92)	0.445 (0.165, 1.201) 0.1018	
G1	8	3 (37.5)	N.A. (0.10, N.A.)	8	8 (100.0)	0.30 (0.10, 3.81)	0.138 (0.028, 0.672) 0.0044	
G2	58	34 (58.6)	2.83 (1.41, 14.69)	50	35 (70.0)	1.87 (0.23, 4.80)	0.663 (0.411, 1.067) 0.0902	
G3	28	17 (60.7)	8.54 (2.27, 17.51)	36	18 (50.0)	3.25 (1.94, N.A.)	0.834 (0.410, 1.696) 0.6242	
NOT OTHERWISE SPECIFIED	51	31 (60.8)	3.94 (2.30, 6.14)	37	26 (70.3)	2.00 (0.99, 4.63)	0.641 (0.375, 1.097) 0.1046	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 72 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.4065
UPPER THORACIC	37	21 (56.8)	3.94 (2.30, N.A.)	25	19 (76.0)	1.91 (0.16, 2.53)	0.517 (0.275, 0.974) 0.0396	
MIDDLE THORACIC	50	27 (54.0)	4.93 (1.91, N.A.)	52	39 (75.0)	1.91 (0.30, 3.22)	0.561 (0.343, 0.917) 0.0198	
LOWER THORACIC	59	40 (67.8)	3.25 (2.07, 6.47)	60	39 (65.0)	2.04 (0.49, 4.96)	0.771 (0.487, 1.219) 0.2684	
GASTROESOPHAGEAL JUNCTION	11	5 (45.5)	8.54 (0.85, N.A.)	8	2 (25.0)	N.A. (0.07, N.A.)	1.587 (0.304, 8.276) 0.5805	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 73 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.2497
RECURRENT - LOCO-REGIONAL	8	3 (37.5)	N.A. (1.87, N.A.)	13	10 (76.9)	0.99 (0.10, N.A.)	0.230 (0.062, 0.856) 0.0179	
RECURRENT - DISTANT	25	13 (52.0)	3.98 (2.10, N.A.)	27	17 (63.0)	1.22 (0.13, N.A.)	0.647 (0.313, 1.337) 0.2445	
DE NOVO METASTATIC	107	66 (61.7)	3.88 (1.91, 6.31)	81	53 (65.4)	2.79 (1.87, 4.53)	0.789 (0.545, 1.143) 0.2125	
UNRESECTABLE ADVANCED	18	12 (66.7)	6.47 (0.20, 12.65)	24	19 (79.2)	0.99 (0.20, 2.17)	0.563 (0.268, 1.185) 0.1286	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 74 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.1712
CURRENT/FORMER	136	83 (61.0)	3.88 (2.27, 6.08)	111	76 (68.5)	2.04 (1.22, 3.81)	0.721 (0.525, 0.988) 0.0427	
NEVER/UNKNOWN	22	11 (50.0)	17.51 (2.33, N.A.)	34	23 (67.6)	1.10 (0.13, 4.53)	0.422 (0.194, 0.919) 0.0262	
ALCOHOL USE								0.5738
CURRENT/FORMER	126	76 (60.3)	3.88 (2.30, 6.31)	117	80 (68.4)	1.97 (1.15, 2.83)	0.685 (0.499, 0.942) 0.0203	
NEVER/UNKNOWN	32	18 (56.3)	6.37 (2.27, 25.63)	28	19 (67.9)	2.37 (0.20, 4.63)	0.555 (0.280, 1.099) 0.0865	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 75 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.0771
<= 1	80	46 (57.5)	4.90 (2.89, 12.65)	69	52 (75.4)	1.91 (0.36, 2.17)	0.509 (0.339, 0.763) 0.0009	
>= 2	78	48 (61.5)	2.73 (1.84, 6.37)	76	47 (61.8)	2.63 (1.15, 4.80)	0.843 (0.560, 1.270) 0.4262	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.0799
< 1 YEAR	128	83 (64.8)	3.88 (1.91, 6.14)	115	79 (68.7)	2.00 (1.35, 2.92)	0.754 (0.550, 1.033) 0.0803	
1 - < 3 YEARS	25	9 (36.0)	N.A. (3.06, N.A.)	21	13 (61.9)	0.99 (0.07, N.A.)	0.390 (0.166, 0.918) 0.0279	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 76 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.7676
YES	38	24 (63.2)	3.71 (2.07, 8.54)	37	26 (70.3)	1.22 (0.20, 3.25)	0.596 (0.339, 1.050) 0.0714	
NO	120	70 (58.3)	4.57 (2.66, 8.84)	108	73 (67.6)	2.07 (1.35, 4.30)	0.676 (0.484, 0.945) 0.0220	
PRIOR RADIOTHERAPY								0.2040
YES	26	10 (38.5)	N.A. (2.30, N.A.)	27	17 (63.0)	0.99 (0.16, N.A.)	0.421 (0.192, 0.922) 0.0270	
NO	132	84 (63.6)	3.94 (2.14, 6.31)	118	82 (69.5)	1.97 (1.22, 2.92)	0.711 (0.521, 0.970) 0.0314	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 77 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.8992
< 10	53	30 (56.6)	3.71 (1.51, N.A.)	54	36 (66.7)	1.91 (0.36, 2.63)	0.684 (0.420, 1.111) 0.1264	
>= 10	92	56 (60.9)	3.94 (2.33, 8.54)	89	61 (68.5)	2.00 (0.99, 4.30)	0.688 (0.475, 0.996) 0.0488	
PD-L1 CPS II								0.4315
< 5	29	20 (69.0)	1.68 (0.36, 6.08)	24	18 (75.0)	1.61 (0.26, 5.06)	0.872 (0.460, 1.655) 0.6767	
>= 5	116	66 (56.9)	4.90 (2.73, 12.39)	119	79 (66.4)	2.04 (1.02, 3.25)	0.641 (0.460, 0.895) 0.0090	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 78 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.0835
< 10%	55	35 (63.6)	3.88 (1.84, 6.31)	57	35 (61.4)	2.79 (1.87, 5.13)	0.891 (0.554, 1.432) 0.6409	
>= 10%	103	59 (57.3)	4.57 (2.46, 14.69)	88	64 (72.7)	1.35 (0.62, 2.53)	0.547 (0.381, 0.787) 0.0011	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.0781
< 5%	38	24 (63.2)	3.98 (1.84, 8.84)	41	23 (56.1)	4.53 (1.15, N.A.)	0.988 (0.552, 1.767) 0.9782	
>= 5%	120	70 (58.3)	4.57 (2.33, 12.65)	104	76 (73.1)	1.91 (0.85, 2.17)	0.566 (0.406, 0.789) 0.0007	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 79 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	44 (27.8)	N.A. (24.02, N.A.)	145	22 (15.2)	N.A.	1.975 (1.179, 3.310) 0.0086	
AGE								0.3729
< 65	95	24 (25.3)	N.A.	75	14 (18.7)	N.A.	1.553 (0.802, 3.004) 0.1885	
>= 65 AND < 75	55	19 (34.5)	24.02 (6.05, N.A.)	58	7 (12.1)	N.A.	2.930 (1.214, 7.073) 0.0124	
>= 75	8	1 (12.5)	N.A. (0.13, N.A.)	12	1 (8.3)	N.A.	1.535 (0.096, 24.550) 0.7600	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 80 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9564
MALE	131	37 (28.2)	N.A. (24.02, N.A.)	122	19 (15.6)	N.A.	2.000 (1.146, 3.490) 0.0130	
FEMALE	27	7 (25.9)	25.63 (25.63, N.A.)	23	3 (13.0)	N.A.	1.887 (0.472, 7.549) 0.3613	
RACE								0.3795
ASIAN	117	38 (32.5)	25.63 (24.02, N.A.)	104	17 (16.3)	N.A.	2.172 (1.219, 3.869) 0.0071	
NON-ASIAN	41	6 (14.6)	N.A.	41	5 (12.2)	N.A.	1.252 (0.382, 4.107) 0.7095	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 81 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4945
J/K/T	91	30 (33.0)	25.63 (24.02, N.A.)	85	13 (15.3)	N.A.	2.431 (1.258, 4.699) 0.0064	
REST OF ASIA	25	8 (32.0)	N.A. (2.30, N.A.)	19	4 (21.1)	N.A. (3.25, N.A.)	1.506 (0.453, 5.008) 0.5056	
REST OF WORLD	42	6 (14.3)	N.A.	41	5 (12.2)	N.A.	1.213 (0.370, 3.978) 0.7500	
REGION								0.3460
ASIA	116	38 (32.8)	25.63 (24.02, N.A.)	104	17 (16.3)	N.A.	2.199 (1.234, 3.918) 0.0062	
NON-ASIA	42	6 (14.3)	N.A.	41	5 (12.2)	N.A.	1.213 (0.370, 3.978) 0.7500	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 82 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.5323
0	71	23 (32.4)	25.63 (25.63, N.A.)	69	13 (18.8)	N.A.	1.781 (0.897, 3.537) 0.0953	
1	87	21 (24.1)	N.A. (24.02, N.A.)	74	8 (10.8)	N.A.	2.421 (1.065, 5.501) 0.0295	
WEIGHT								0.2148
< 60 KG	96	25 (26.0)	N.A. (25.63, N.A.)	76	14 (18.4)	N.A.	1.512 (0.782, 2.924) 0.2183	
>= 60 KG	62	19 (30.6)	N.A. (7.49, N.A.)	69	8 (11.6)	N.A.	2.863 (1.244, 6.592) 0.0097	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 83 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.3035
STAGE I	5	1 (20.0)	N.A. (2.00, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	2 (40.0)	N.A. (2.30, N.A.)	5	0	N.E.	N.E. 0.2457	
STAGE III	33	5 (15.2)	N.A.	46	9 (19.6)	N.A.	0.755 (0.253, 2.258) 0.6144	
STAGE IV	114	35 (30.7)	25.63 (24.02, N.A.)	89	13 (14.6)	N.A.	2.366 (1.244, 4.501) 0.0069	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 84 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2117
GX	11	4 (36.4)	25.63 (0.13, N.A.)	14	0	N.E.	N.E. 0.0400	
G1	8	1 (12.5)	N.A. (1.38, N.A.)	8	3 (37.5)	N.A. (1.05, N.A.)	0.304 (0.032, 2.930) 0.2752	
G2	58	17 (29.3)	N.A.	50	9 (18.0)	N.A.	1.766 (0.787, 3.965) 0.1627	
G3	28	7 (25.0)	24.02 (24.02, N.A.)	36	1 (2.8)	N.A.	8.288 (0.997, 68.898) 0.0193	
NOT OTHERWISE SPECIFIED	51	13 (25.5)	N.A.	37	9 (24.3)	N.A.	1.104 (0.471, 2.587) 0.8251	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 85 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.3783
UPPER THORACIC	37	11 (29.7)	N.A. (4.90, N.A.)	25	5 (20.0)	N.A. (5.36, N.A.)	1.559 (0.541, 4.496) 0.4066	
MIDDLE THORACIC	50	14 (28.0)	N.A. (6.05, N.A.)	52	12 (23.1)	N.A.	1.365 (0.631, 2.955) 0.4304	
LOWER THORACIC	59	17 (28.8)	25.63 (24.02, N.A.)	60	5 (8.3)	N.A.	3.454 (1.254, 9.514) 0.0109	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (2.33, N.A.)	8	0	N.E.	N.E. 0.4028	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 86 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5487
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	N.A. (2.33, N.A.)	13	3 (23.1)	N.A. (2.53, N.A.)	1.003 (0.167, 6.007) 0.9976	
RECURRENT - DISTANT	25	3 (12.0)	N.A.	27	3 (11.1)	N.A.	1.044 (0.211, 5.173) 0.9581	
DE NOVO METASTATIC	107	33 (30.8)	25.63 (24.02, N.A.)	81	11 (13.6)	N.A.	2.551 (1.281, 5.082) 0.0058	
UNRESECTABLE ADVANCED	18	6 (33.3)	N.A. (3.42, N.A.)	24	5 (20.8)	N.A. (5.36, N.A.)	1.780 (0.543, 5.836) 0.3347	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 87 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.7564
CURRENT/FORMER	136	38 (27.9)	N.A. (24.02, N.A.)	111	18 (16.2)	N.A.	1.898 (1.080, 3.335) 0.0237	
NEVER/UNKNOWN	22	6 (27.3)	25.63 (3.42, N.A.)	34	4 (11.8)	N.A. (8.64, N.A.)	2.128 (0.571, 7.935) 0.2520	
ALCOHOL USE								0.1155
CURRENT/FORMER	126	38 (30.2)	N.A. (24.02, N.A.)	117	16 (13.7)	N.A.	2.464 (1.370, 4.432) 0.0019	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (25.63, N.A.)	28	6 (21.4)	N.A.	0.799 (0.244, 2.620) 0.6985	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 88 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.2773
<= 1	80	23 (28.8)	N.A. (24.02, N.A.)	69	14 (20.3)	N.A.	1.523 (0.779, 2.978) 0.2179	
>= 2	78	21 (26.9)	N.A. (25.63, N.A.)	76	8 (10.5)	N.A.	2.748 (1.209, 6.246) 0.0119	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9134
< 1 YEAR	128	40 (31.3)	25.63 (24.02, N.A.)	115	20 (17.4)	N.A.	2.002 (1.164, 3.443) 0.0107	
1 - < 3 YEARS	25	3 (12.0)	N.A. (7.49, N.A.)	21	1 (4.8)	N.A.	2.239 (0.233, 21.535) 0.4734	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 89 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.8676
YES	38	9 (23.7)	N.A.	37	4 (10.8)	N.A.	2.267 (0.698, 7.366) 0.1614	
NO	120	35 (29.2)	25.63 (24.02, N.A.)	108	18 (16.7)	N.A.	1.906 (1.073, 3.388) 0.0257	
PRIOR RADIOTHERAPY								0.3810
YES	26	3 (11.5)	N.A. (7.49, N.A.)	27	3 (11.1)	N.A.	1.033 (0.208, 5.124) 0.9687	
NO	132	41 (31.1)	N.A. (24.02, N.A.)	118	19 (16.1)	N.A.	2.131 (1.230, 3.689) 0.0058	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 90 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.8745
< 10	53	15 (28.3)	N.A.	54	8 (14.8)	N.A.	2.036 (0.863, 4.804) 0.0975	
>= 10	92	27 (29.3)	25.63 (24.02, N.A.)	89	13 (14.6)	N.A.	2.215 (1.132, 4.332) 0.0175	
PD-L1 CPS II								0.6281
< 5	29	9 (31.0)	N.A. (1.68, N.A.)	24	3 (12.5)	N.A.	3.076 (0.831, 11.383) 0.0763	
>= 5	116	33 (28.4)	25.63 (24.02, N.A.)	119	18 (15.1)	N.A.	2.000 (1.118, 3.577) 0.0175	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 91 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.4122
< 10%	55	18 (32.7)	N.A. (6.05, N.A.)	57	12 (21.1)	N.A. (8.64, N.A.)	1.636 (0.787, 3.400) 0.1840	
>= 10%	103	26 (25.2)	N.A. (24.02, N.A.)	88	10 (11.4)	N.A.	2.442 (1.167, 5.110) 0.0146	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7202
< 5%	38	11 (28.9)	N.A. (6.05, N.A.)	41	7 (17.1)	N.A. (8.64, N.A.)	1.778 (0.689, 4.590) 0.2277	
>= 5%	120	33 (27.5)	N.A. (24.02, N.A.)	104	15 (14.4)	N.A.	2.084 (1.124, 3.864) 0.0174	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 92 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	19 (12.0)	N.A.	145	32 (22.1)	N.A.	0.495 (0.280, 0.876) 0.0139	
AGE								0.9460
< 65	95	7 (7.4)	N.A.	75	11 (14.7)	N.A.	0.471 (0.182, 1.220) 0.1130	
>= 65 AND < 75	55	9 (16.4)	N.A. (7.85, N.A.)	58	16 (27.6)	N.A. (7.85, N.A.)	0.521 (0.229, 1.183) 0.1141	
>= 75	8	3 (37.5)	N.A. (0.13, N.A.)	12	5 (41.7)	N.A. (0.20, N.A.)	0.751 (0.179, 3.156) 0.6945	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 93 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2719
MALE	131	15 (11.5)	N.A.	122	29 (23.8)	N.A.	0.431 (0.230, 0.807) 0.0069	
FEMALE	27	4 (14.8)	N.A.	23	3 (13.0)	N.A.	1.098 (0.246, 4.909) 0.9026	
RACE								0.9997
ASIAN	117	19 (16.2)	N.A.	104	32 (30.8)	N.A.	0.458 (0.259, 0.810) 0.0061	
NON-ASIAN	41	0	N.E.	41	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 94 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.1976
J/K/T	91	15 (16.5)	N.A.	85	31 (36.5)	N.A. (6.54, N.A.)	0.378 (0.203, 0.703) 0.0014	
REST OF ASIA	25	4 (16.0)	N.A.	19	1 (5.3)	N.A.	2.972 (0.332, 26.595) 0.3064	
REST OF WORLD	42	0	N.E.	41	0	N.E.	N.E. N.E.	
REGION								0.9997
ASIA	116	19 (16.4)	N.A.	104	32 (30.8)	N.A.	0.463 (0.262, 0.819) 0.0068	
NON-ASIA	42	0	N.E.	41	0	N.E.	N.E. N.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 95 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.3491
0	71	16 (22.5)	N.A.	69	23 (33.3)	N.A. (7.85, N.A.)	0.559 (0.295, 1.061) 0.0728	
1	87	3 (3.4)	N.A.	74	9 (12.2)	N.A.	0.300 (0.081, 1.110) 0.0557	
WEIGHT								0.5611
< 60 KG	96	13 (13.5)	N.A.	76	17 (22.4)	N.A.	0.577 (0.280, 1.189) 0.1322	
>= 60 KG	62	6 (9.7)	N.A.	69	15 (21.7)	N.A.	0.372 (0.141, 0.976) 0.0372	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 96 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8886
STAGE I	5	0	N.E.	5	2 (40.0)	N.A. (0.49, N.A.)	N.E. 0.1343	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	3 (9.1)	N.A.	46	11 (23.9)	N.A.	0.348 (0.097, 1.246) 0.0899	
STAGE IV	114	15 (13.2)	N.A.	89	19 (21.3)	N.A.	0.574 (0.291, 1.134) 0.1067	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 97 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.6538
GX	11	2 (18.2)	N.A. (2.86, N.A.)	14	8 (57.1)	3.07 (0.13, N.A.)	0.276 (0.059, 1.303) 0.0805	
G1	8	0	N.E.	8	3 (37.5)	N.A. (0.23, N.A.)	N.E. 0.0719	
G2	58	5 (8.6)	N.A.	50	6 (12.0)	N.A.	0.691 (0.211, 2.264) 0.5390	
G3	28	4 (14.3)	N.A. (12.65, N.A.)	36	4 (11.1)	N.A.	1.031 (0.241, 4.417) 0.9678	
NOT OTHERWISE SPECIFIED	51	8 (15.7)	N.A.	37	11 (29.7)	N.A. (7.85, N.A.)	0.455 (0.182, 1.137) 0.0845	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 98 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.5581
UPPER THORACIC	37	6 (16.2)	N.A.	25	4 (16.0)	N.A. (6.54, N.A.)	1.010 (0.284, 3.592) 0.9917	
MIDDLE THORACIC	50	8 (16.0)	N.A.	52	14 (26.9)	N.A.	0.560 (0.235, 1.335) 0.1877	
LOWER THORACIC	59	5 (8.5)	N.A.	60	14 (23.3)	N.A.	0.272 (0.093, 0.794) 0.0111	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 99 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3758
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	2 (15.4)	N.A. (1.35, N.A.)	N.E. 0.2468	
RECURRENT - DISTANT	25	1 (4.0)	N.A.	27	7 (25.9)	N.A.	0.136 (0.017, 1.108) 0.0288	
DE NOVO METASTATIC	107	12 (11.2)	N.A.	81	16 (19.8)	N.A.	0.548 (0.259, 1.159) 0.1107	
UNRESECTABLE ADVANCED	18	6 (33.3)	N.A. (0.95, N.A.)	24	7 (29.2)	N.A. (6.54, N.A.)	0.991 (0.329, 2.986) 0.9894	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 100 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.7841
CURRENT/FORMER	136	17 (12.5)	N.A.	111	27 (24.3)	N.A.	0.456 (0.247, 0.841) 0.0100	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	5 (14.7)	N.A.	0.588 (0.114, 3.032) 0.5211	
ALCOHOL USE								0.2204
CURRENT/FORMER	126	15 (11.9)	N.A.	117	29 (24.8)	N.A.	0.421 (0.225, 0.789) 0.0055	
NEVER/UNKNOWN	32	4 (12.5)	N.A.	28	3 (10.7)	N.A.	1.196 (0.267, 5.349) 0.8142	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 101 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.1272
<= 1	80	8 (10.0)	N.A.	69	19 (27.5)	N.A.	0.310 (0.135, 0.712) 0.0035	
>= 2	78	11 (14.1)	N.A.	76	13 (17.1)	N.A.	0.818 (0.366, 1.826) 0.6267	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.4696
< 1 YEAR	128	18 (14.1)	N.A.	115	26 (22.6)	N.A.	0.569 (0.311, 1.042) 0.0651	
1 - < 3 YEARS	25	1 (4.0)	N.A.	21	3 (14.3)	N.A.	0.242 (0.025, 2.330) 0.1842	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 102 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.0683
YES	38	1 (2.6)	N.A.	37	9 (24.3)	N.A.	0.092 (0.012, 0.726) 0.0046	
NO	120	18 (15.0)	N.A.	108	23 (21.3)	N.A.	0.656 (0.353, 1.219) 0.1805	
PRIOR RADIOTHERAPY								0.7090
YES	26	1 (3.8)	N.A.	27	3 (11.1)	N.A.	0.330 (0.034, 3.169) 0.3141	
NO	132	18 (13.6)	N.A.	118	29 (24.6)	N.A.	0.499 (0.276, 0.902) 0.0191	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 103 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.4261
< 10	53	5 (9.4)	N.A.	54	7 (13.0)	N.A.	0.724 (0.230, 2.281) 0.5790	
>= 10	92	11 (12.0)	N.A.	89	24 (27.0)	N.A.	0.394 (0.193, 0.808) 0.0085	
PD-L1 CPS II								0.8614
< 5	29	2 (6.9)	N.A.	24	4 (16.7)	N.A.	0.440 (0.081, 2.405) 0.3301	
>= 5	116	14 (12.1)	N.A.	119	27 (22.7)	N.A.	0.475 (0.248, 0.909) 0.0217	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 104 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3276
< 10%	55	5 (9.1)	N.A.	57	6 (10.5)	N.A.	0.838 (0.256, 2.750) 0.7709	
>= 10%	103	14 (13.6)	N.A.	88	26 (29.5)	N.A.	0.404 (0.210, 0.777) 0.0050	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.0162*
< 5%	38	5 (13.2)	N.A.	41	1 (2.4)	N.A.	5.620 (0.656, 48.127) 0.0754	
>= 5%	120	14 (11.7)	N.A.	104	31 (29.8)	N.A.	0.340 (0.180, 0.642) 0.0005	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 105 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	1 (0.6)	N.A.	145	19 (13.1)	N.A.	<0.001 (<0.001, N.A.) <0.0001	
AGE								>0.9999
< 65	95	1 (1.1)	N.A. (24.77, N.A.)	75	15 (20.0)	N.A.	<0.001 (<0.001, N.A.) <0.0001	
>= 65 AND < 75	55	0	N.E.	58	3 (5.2)	N.A.	N.E. 0.0889	
>= 75	8	0	N.E.	12	1 (8.3)	N.A.	N.E. 0.4250	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 106 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9940
MALE	131	1 (0.8)	N.A.	122	13 (10.7)	N.A.	<0.001 (<0.001, N.A.) <0.0001	
FEMALE	27	0	N.E.	23	6 (26.1)	N.A. (3.84, N.A.)	N.E. 0.0050	
RACE								0.9940
ASIAN	117	1 (0.9)	N.A. (24.77, N.A.)	104	8 (7.7)	N.A.	<0.001 (<0.001, N.A.) 0.0015	
NON-ASIAN	41	0	N.E.	41	11 (26.8)	N.A.	N.E. 0.0005	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 107 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								>0.9999
J/K/T	91	1 (1.1)	N.A. (24.77, N.A.)	85	8 (9.4)	N.A.	<0.001 (<0.001, N.A.) 0.0020	
REST OF ASIA	25	0	N.E.	19	0	N.E.	N.E. N.E.	
REST OF WORLD	42	0	N.E.	41	11 (26.8)	N.A.	N.E. 0.0004	
REGION								0.9940
ASIA	116	1 (0.9)	N.A. (24.77, N.A.)	104	8 (7.7)	N.A.	<0.001 (<0.001, N.A.) 0.0016	
NON-ASIA	42	0	N.E.	41	11 (26.8)	N.A.	N.E. 0.0004	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 108 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9956
0	71	0	N.E.	69	6 (8.7)	N.A.	N.E. 0.0081	
1	87	1 (1.1)	N.A. (24.77, N.A.)	74	12 (16.2)	N.A.	<0.001 (<0.001, N.A.) 0.0001	
WEIGHT								0.9943
< 60 KG	96	0	N.E.	76	10 (13.2)	N.A.	N.E. 0.0003	
>= 60 KG	62	1 (1.6)	N.A. (24.77, N.A.)	69	9 (13.0)	N.A.	<0.001 (<0.001, N.A.) 0.0025	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 109 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	0	N.E.	5	1 (20.0)	N.A. (6.18, N.A.)	N.E. 0.2482	
STAGE II	5	0	N.E.	5	1 (20.0)	N.A. (3.25, N.A.)	N.E. 0.1967	
STAGE III	33	0	N.E.	46	6 (13.0)	N.A.	N.E. 0.0338	
STAGE IV	114	1 (0.9)	N.A. (24.77, N.A.)	89	11 (12.4)	N.A.	<0.001 (<0.001, N.A.) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 110 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								>0.9999
GX	11	0	N.E.	14	0	N.E.	N.E. N.E.	
G1	8	0	N.E.	8	0	N.E.	N.E. N.E.	
G2	58	1 (1.7)	N.A. (24.77, N.A.)	50	12 (24.0)	N.A. (8.61, N.A.)	<0.001 (<0.001, N.A.) <0.0001	
G3	28	0	N.E.	36	5 (13.9)	N.A.	N.E. 0.0454	
NOT OTHERWISE SPECIFIED	51	0	N.E.	37	2 (5.4)	N.A.	N.E. 0.0979	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 111 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								>0.9999
UPPER THORACIC	37	0	N.E.	25	2 (8.0)	N.A.	N.E. 0.0843	
MIDDLE THORACIC	50	1 (2.0)	N.A. (24.77, N.A.)	52	11 (21.2)	N.A.	<0.001 (<0.001, N.A.) 0.0007	
LOWER THORACIC	59	0	N.E.	60	6 (10.0)	N.A.	N.E. 0.0085	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 112 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	4 (30.8)	N.A. (0.36, N.A.)	N.E. 0.0892	
RECURRENT - DISTANT	25	0	N.E.	27	2 (7.4)	N.A.	N.E. 0.1615	
DE NOVO METASTATIC	107	0	N.E.	81	11 (13.6)	N.A.	N.E. <0.0001	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A. (24.77, N.A.)	24	2 (8.3)	N.A.	<0.001 (<0.001, N.A.) 0.2189	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 113 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9932
CURRENT/FORMER	136	1 (0.7)	N.A. (24.77, N.A.)	111	11 (9.9)	N.A.	<0.001 (<0.001, N.A.) 0.0002	
NEVER/UNKNOWN	22	0	N.E.	34	8 (23.5)	N.A. (8.61, N.A.)	N.E. 0.0149	
ALCOHOL USE								0.9932
CURRENT/FORMER	126	1 (0.8)	N.A. (24.77, N.A.)	117	12 (10.3)	N.A.	<0.001 (<0.001, N.A.) 0.0002	
NEVER/UNKNOWN	32	0	N.E.	28	7 (25.0)	N.A.	N.E. 0.0038	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 114 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9945
<= 1	80	0	N.E.	69	9 (13.0)	N.A.	N.E. 0.0007	
>= 2	78	1 (1.3)	N.A. (24.77, N.A.)	76	10 (13.2)	N.A.	<0.001 (<0.001, N.A.) 0.0011	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9955
< 1 YEAR	128	1 (0.8)	N.A. (24.77, N.A.)	115	14 (12.2)	N.A.	<0.001 (<0.001, N.A.) <0.0001	
1 - < 3 YEARS	25	0	N.E.	21	5 (23.8)	N.A. (6.18, N.A.)	N.E. 0.0117	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 115 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9961
YES	38	0	N.E.	37	5 (13.5)	N.A.	N.E. 0.0167	
NO	120	1 (0.8)	N.A. (24.77, N.A.)	108	14 (13.0)	N.A.	<0.001 (<0.001, N.A.) <0.0001	
PRIOR RADIOTHERAPY								0.9953
YES	26	0	N.E.	27	5 (18.5)	N.A.	N.E. 0.0240	
NO	132	1 (0.8)	N.A.	118	14 (11.9)	N.A.	<0.001 (<0.001, N.A.) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 116 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9939
< 10	53	1 (1.9)	N.A. (24.77, N.A.)	54	8 (14.8)	N.A.	<0.001 (<0.001, N.A.) 0.0039	
>= 10	92	0	N.E.	89	10 (11.2)	N.A.	N.E. 0.0011	
PD-L1 CPS II								0.9927
< 5	29	1 (3.4)	24.77 (N.A., N.A.)	24	2 (8.3)	N.A.	<0.001 (<0.001, N.A.) 0.1288	
>= 5	116	0	N.E.	119	16 (13.4)	N.A.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 117 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9936
< 10%	55	1 (1.8)	N.A. (24.77, N.A.)	57	7 (12.3)	N.A. (8.61, N.A.)	<0.001 (<0.001, N.A.) 0.0029	
>= 10%	103	0	N.E.	88	12 (13.6)	N.A.	N.E. 0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9932
< 5%	38	1 (2.6)	N.A. (24.77, N.A.)	41	5 (12.2)	N.A. (8.61, N.A.)	<0.001 (<0.001, N.A.) 0.0147	
>= 5%	120	0	N.E.	104	14 (13.5)	N.A.	N.E. <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 118 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	93 (58.9)	4.73 (3.29, 6.54)	145	105 (72.4)	0.99 (0.43, 2.56)	0.530 (0.399, 0.703) <0.0001	
AGE								0.2365
< 65	95	55 (57.9)	5.36 (3.25, 6.93)	75	51 (68.0)	1.87 (0.92, 3.98)	0.640 (0.435, 0.940) 0.0226	
>= 65 AND < 75	55	33 (60.0)	3.88 (2.07, 6.54)	58	45 (77.6)	0.46 (0.16, 2.69)	0.472 (0.298, 0.748) 0.0012	
>= 75	8	5 (62.5)	7.16 (0.13, N.A.)	12	9 (75.0)	0.34 (0.07, 3.91)	0.272 (0.072, 1.032) 0.0417	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 119 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8578
MALE	131	78 (59.5)	4.73 (3.25, 6.93)	122	89 (73.0)	0.95 (0.26, 2.27)	0.516 (0.378, 0.704) <0.0001	
FEMALE	27	15 (55.6)	6.05 (2.17, N.A.)	23	16 (69.6)	1.94 (0.26, 5.32)	0.599 (0.296, 1.214) 0.1567	
RACE								0.7053
ASIAN	117	74 (63.2)	4.40 (2.89, 6.51)	104	79 (76.0)	0.69 (0.20, 1.81)	0.494 (0.357, 0.683) <0.0001	
NON-ASIAN	41	19 (46.3)	6.21 (3.42, N.A.)	41	26 (63.4)	3.48 (0.92, 6.70)	0.594 (0.328, 1.075) 0.0831	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 120 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4726
J/K/T	91	57 (62.6)	4.73 (2.89, 6.54)	85	66 (77.6)	0.26 (0.13, 1.05)	0.446 (0.309, 0.643) <0.0001	
REST OF ASIA	25	16 (64.0)	3.38 (0.95, 6.93)	19	13 (68.4)	2.56 (0.23, 3.98)	0.704 (0.335, 1.481) 0.3542	
REST OF WORLD	42	20 (47.6)	6.21 (3.42, N.A.)	41	26 (63.4)	3.48 (0.92, 6.70)	0.620 (0.345, 1.112) 0.1061	
REGION								0.5916
ASIA	116	73 (62.9)	4.73 (2.92, 6.51)	104	79 (76.0)	0.69 (0.20, 1.81)	0.489 (0.353, 0.677) <0.0001	
NON-ASIA	42	20 (47.6)	6.21 (3.42, N.A.)	41	26 (63.4)	3.48 (0.92, 6.70)	0.620 (0.345, 1.112) 0.1061	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 121 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.0026*
0	71	43 (60.6)	5.22 (3.25, 12.65)	69	56 (81.2)	0.23 (0.13, 0.92)	0.352 (0.233, 0.530) <0.0001	
1	87	50 (57.5)	4.63 (2.33, 6.54)	74	47 (63.5)	3.48 (1.15, 4.70)	0.791 (0.528, 1.185) 0.2564	
WEIGHT								0.7082
< 60 KG	96	55 (57.3)	6.01 (3.42, 6.93)	76	53 (69.7)	1.05 (0.26, 3.06)	0.546 (0.371, 0.803) 0.0019	
>= 60 KG	62	38 (61.3)	3.55 (2.00, 7.13)	69	52 (75.4)	0.92 (0.23, 2.27)	0.523 (0.342, 0.799) 0.0025	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 122 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.4269
STAGE I	5	5 (100.0)	2.00 (0.89, N.A.)	5	3 (60.0)	9.56 (0.10, N.A.)	1.049 (0.232, 4.742) 0.9150	
STAGE II	5	2 (40.0)	7.16 (1.41, N.A.)	5	3 (60.0)	0.92 (0.03, N.A.)	0.375 (0.057, 2.449) 0.2906	
STAGE III	33	20 (60.6)	5.22 (3.42, 7.13)	46	35 (76.1)	0.49 (0.20, 1.94)	0.414 (0.235, 0.727) 0.0017	
STAGE IV	114	65 (57.0)	4.63 (3.12, 6.93)	89	64 (71.9)	1.81 (0.43, 3.06)	0.572 (0.403, 0.812) 0.0017	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 123 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9656
GX	11	7 (63.6)	4.14 (0.13, N.A.)	14	11 (78.6)	0.16 (0.07, 1.08)	0.540 (0.208, 1.404) 0.2077	
G1	8	5 (62.5)	6.54 (0.03, N.A.)	8	7 (87.5)	1.46 (0.07, 4.70)	0.402 (0.114, 1.415) 0.1419	
G2	58	34 (58.6)	4.40 (2.17, 12.32)	50	35 (70.0)	1.05 (0.39, 4.60)	0.563 (0.350, 0.908) 0.0179	
G3	28	16 (57.1)	3.88 (1.05, N.A.)	36	26 (72.2)	2.27 (0.33, 4.21)	0.572 (0.300, 1.091) 0.0873	
NOT OTHERWISE SPECIFIED	51	31 (60.8)	5.36 (3.25, 6.51)	37	26 (70.3)	0.53 (0.20, 3.06)	0.538 (0.317, 0.913) 0.0206	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 124 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7466
UPPER THORACIC	37	24 (64.9)	3.42 (2.76, 4.73)	25	17 (68.0)	1.08 (0.13, 4.70)	0.664 (0.355, 1.242) 0.2070	
MIDDLE THORACIC	50	26 (52.0)	6.05 (2.89, 20.80)	52	37 (71.2)	1.15 (0.53, 3.75)	0.519 (0.312, 0.863) 0.0107	
LOWER THORACIC	59	36 (61.0)	5.36 (1.41, 12.65)	60	47 (78.3)	0.38 (0.20, 1.87)	0.459 (0.292, 0.722) 0.0006	
GASTROESOPHAGEAL JUNCTION	11	6 (54.5)	12.32 (0.49, N.A.)	8	4 (50.0)	6.70 (0.07, N.A.)	0.489 (0.120, 1.982) 0.2939	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 125 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5598
RECURRENT - LOCO-REGIONAL	8	4 (50.0)	12.09 (0.23, N.A.)	13	7 (53.8)	5.32 (0.10, N.A.)	0.502 (0.128, 1.961) 0.3220	
RECURRENT - DISTANT	25	14 (56.0)	6.05 (2.76, 7.16)	27	22 (81.5)	0.23 (0.13, 2.63)	0.353 (0.179, 0.696) 0.0019	
DE NOVO METASTATIC	107	59 (55.1)	4.73 (2.99, 9.49)	81	57 (70.4)	1.84 (0.85, 3.75)	0.567 (0.392, 0.822) 0.0025	
UNRESECTABLE ADVANCED	18	16 (88.9)	3.35 (0.89, 4.40)	24	19 (79.2)	0.44 (0.13, 2.76)	0.643 (0.327, 1.265) 0.2004	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 126 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.0707
CURRENT/FORMER	136	85 (62.5)	3.88 (2.99, 6.51)	111	78 (70.3)	1.05 (0.26, 2.63)	0.585 (0.428, 0.800) 0.0008	
NEVER/UNKNOWN	22	8 (36.4)	6.21 (4.14, N.A.)	34	27 (79.4)	0.94 (0.26, 2.76)	0.285 (0.129, 0.631) 0.0010	
ALCOHOL USE								0.5173
CURRENT/FORMER	126	76 (60.3)	4.40 (2.99, 6.31)	117	83 (70.9)	1.05 (0.26, 2.63)	0.555 (0.404, 0.762) 0.0003	
NEVER/UNKNOWN	32	17 (53.1)	6.54 (3.12, N.A.)	28	22 (78.6)	0.97 (0.26, 3.06)	0.451 (0.239, 0.853) 0.0123	

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(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 127 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.5511
<= 1	80	48 (60.0)	4.73 (3.38, 7.13)	69	50 (72.5)	1.94 (0.39, 4.21)	0.570 (0.381, 0.852) 0.0057	
>= 2	78	45 (57.7)	4.14 (2.89, 6.54)	76	55 (72.4)	0.92 (0.20, 1.81)	0.498 (0.333, 0.744) 0.0006	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3070
< 1 YEAR	128	79 (61.7)	3.55 (2.99, 6.14)	115	85 (73.9)	1.05 (0.43, 2.69)	0.566 (0.414, 0.772) 0.0003	
1 - < 3 YEARS	25	10 (40.0)	7.16 (5.22, N.A.)	21	14 (66.7)	0.95 (0.23, 9.56)	0.394 (0.174, 0.891) 0.0214	

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Protocol: CA209648 Page 128 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.2609
YES	38	21 (55.3)	6.31 (2.92, 17.05)	37	28 (75.7)	0.39 (0.13, 2.63)	0.396 (0.220, 0.714) 0.0015	
NO	120	72 (60.0)	3.88 (3.12, 6.21)	108	77 (71.3)	1.15 (0.53, 2.79)	0.588 (0.424, 0.814) 0.0013	
PRIOR RADIOTHERAPY								0.8515
YES	26	14 (53.8)	6.05 (1.41, N.A.)	27	17 (63.0)	0.92 (0.10, N.A.)	0.566 (0.274, 1.168) 0.1233	
NO	132	79 (59.8)	4.63 (3.29, 6.51)	118	88 (74.6)	1.05 (0.33, 2.56)	0.520 (0.382, 0.708) <0.0001	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 129 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9158
< 10	53	31 (58.5)	5.22 (2.89, 17.05)	54	39 (72.2)	1.05 (0.33, 3.75)	0.492 (0.301, 0.805) 0.0041	
>= 10	92	53 (57.6)	4.73 (3.25, 6.93)	89	64 (71.9)	0.92 (0.23, 2.76)	0.560 (0.388, 0.806) 0.0018	
PD-L1 CPS II								0.2542
< 5	29	17 (58.6)	2.89 (0.72, N.A.)	24	16 (66.7)	2.20 (0.26, 4.70)	0.738 (0.367, 1.481) 0.3894	
>= 5	116	67 (57.8)	5.36 (3.38, 6.93)	119	87 (73.1)	0.92 (0.26, 2.63)	0.497 (0.360, 0.687) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 130 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3749
< 10%	55	33 (60.0)	4.40 (2.89, 6.54)	57	40 (70.2)	1.87 (0.92, 3.98)	0.579 (0.361, 0.930) 0.0227	
>= 10%	103	60 (58.3)	5.22 (3.12, 7.13)	88	65 (73.9)	0.46 (0.16, 1.94)	0.491 (0.344, 0.701) <0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.5020
< 5%	38	23 (60.5)	4.63 (2.89, 20.70)	41	28 (68.3)	1.84 (0.49, 4.70)	0.586 (0.331, 1.037) 0.0654	
>= 5%	120	70 (58.3)	4.73 (3.12, 6.93)	104	77 (74.0)	0.89 (0.23, 2.27)	0.508 (0.366, 0.705) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 131 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
OVERALL	158	36 (22.8)	N.A. (16.13, N.A.)	145	80 (55.2)	3.91 (1.05, 10.18)	0.268 (0.179, 0.400) <0.0001	
AGE								0.3118
< 65	95	21 (22.1)	N.A. (12.65, N.A.)	75	35 (46.7)	10.18 (2.89, N.A.)	0.359 (0.208, 0.618) 0.0001	
>= 65 AND < 75	55	13 (23.6)	N.A. (16.13, N.A.)	58	37 (63.8)	0.99 (0.20, 5.32)	0.211 (0.109, 0.409) <0.0001	
>= 75	8	2 (25.0)	N.A. (0.13, N.A.)	12	8 (66.7)	0.34 (0.07, N.A.)	0.239 (0.050, 1.146) 0.0526	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 132 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8518
MALE	131	30 (22.9)	N.A. (16.13, N.A.)	122	68 (55.7)	3.81 (0.49, 10.18)	0.261 (0.168, 0.406) <0.0001	
FEMALE	27	6 (22.2)	N.A. (6.14, N.A.)	23	12 (52.2)	5.32 (0.99, N.A.)	0.297 (0.111, 0.798) 0.0113	
RACE								0.5427
ASIAN	117	29 (24.8)	N.A. (12.98, N.A.)	104	63 (60.6)	1.05 (0.23, 5.22)	0.242 (0.154, 0.381) <0.0001	
NON-ASIAN	41	7 (17.1)	N.A. (7.62, N.A.)	41	17 (41.5)	10.74 (3.91, N.A.)	0.330 (0.136, 0.800) 0.0100	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 133 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.3665
J/K/T	91	23 (25.3)	N.A. (16.13, N.A.)	85	56 (65.9)	0.26 (0.16, 2.89)	0.218 (0.132, 0.359) <0.0001	
REST OF ASIA	25	6 (24.0)	12.98 (9.49, N.A.)	19	7 (36.8)	N.A. (1.51, N.A.)	0.400 (0.126, 1.271) 0.1083	
REST OF WORLD	42	7 (16.7)	N.A.	41	17 (41.5)	10.74 (3.91, N.A.)	0.317 (0.131, 0.770) 0.0075	
REGION								0.6032
ASIA	116	29 (25.0)	N.A. (12.98, N.A.)	104	63 (60.6)	1.05 (0.23, 5.22)	0.245 (0.156, 0.385) <0.0001	
NON-ASIA	42	7 (16.7)	N.A.	41	17 (41.5)	10.74 (3.91, N.A.)	0.317 (0.131, 0.770) 0.0075	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 134 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.0276*
0	71	18 (25.4)	N.A. (16.13, N.A.)	69	50 (72.5)	0.26 (0.13, 1.05)	0.171 (0.098, 0.300) <0.0001	
1	87	18 (20.7)	N.A. (12.98, N.A.)	74	29 (39.2)	10.18 (5.22, N.A.)	0.431 (0.238, 0.780) 0.0044	
WEIGHT								0.0253*
< 60 KG	96	15 (15.6)	N.A.	76	43 (56.6)	3.06 (0.53, N.A.)	0.170 (0.093, 0.313) <0.0001	
>= 60 KG	62	21 (33.9)	12.65 (7.13, N.A.)	69	37 (53.6)	5.22 (0.26, 10.74)	0.424 (0.246, 0.731) 0.0016	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 135 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9878
STAGE I	5	1 (20.0)	N.A. (12.98, N.A.)	5	2 (40.0)	N.A. (0.10, N.A.)	<0.001 (<0.001, N.A.) 0.1336	
STAGE II	5	0	N.E.	5	1 (20.0)	N.A. (0.03, N.A.)	N.E. 0.3173	
STAGE III	33	8 (24.2)	N.A. (7.13, N.A.)	46	26 (56.5)	0.99 (0.20, N.A.)	0.249 (0.111, 0.560) 0.0003	
STAGE IV	114	27 (23.7)	N.A. (16.13, N.A.)	89	51 (57.3)	3.81 (1.05, 7.69)	0.284 (0.177, 0.457) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 136 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9366
GX	11	3 (27.3)	N.A. (0.13, N.A.)	14	10 (71.4)	0.16 (0.07, N.A.)	0.263 (0.072, 0.967) 0.0319	
G1	8	3 (37.5)	N.A. (0.03, N.A.)	8	5 (62.5)	2.73 (0.07, N.A.)	0.373 (0.072, 1.934) 0.2193	
G2	58	13 (22.4)	N.A. (9.49, N.A.)	50	25 (50.0)	10.18 (1.05, N.A.)	0.311 (0.158, 0.609) 0.0003	
G3	28	5 (17.9)	N.A. (12.65, N.A.)	36	17 (47.2)	6.70 (3.48, N.A.)	0.215 (0.070, 0.664) 0.0037	
NOT OTHERWISE SPECIFIED	51	12 (23.5)	N.A. (6.54, N.A.)	37	23 (62.2)	0.53 (0.20, N.A.)	0.224 (0.110, 0.453) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 137 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.5216
UPPER THORACIC	37	9 (24.3)	N.A. (9.49, N.A.)	25	10 (40.0)	N.A. (0.13, N.A.)	0.427 (0.172, 1.058) 0.0625	
MIDDLE THORACIC	50	12 (24.0)	N.A. (6.54, N.A.)	52	29 (55.8)	3.19 (0.92, N.A.)	0.308 (0.157, 0.605) 0.0003	
LOWER THORACIC	59	13 (22.0)	N.A. (12.98, N.A.)	60	37 (61.7)	2.89 (0.20, 7.69)	0.189 (0.093, 0.384) <0.0001	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (7.13, N.A.)	8	4 (50.0)	6.70 (0.07, N.A.)	0.108 (0.011, 1.007) 0.0201	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 138 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9399
RECURRENT - LOCO-REGIONAL	8	1 (12.5)	N.A. (7.13, N.A.)	13	5 (38.5)	10.74 (0.10, N.A.)	0.233 (0.027, 2.009) 0.1514	
RECURRENT - DISTANT	25	6 (24.0)	N.A. (6.31, N.A.)	27	14 (51.9)	0.49 (0.13, N.A.)	0.245 (0.088, 0.687) 0.0044	
DE NOVO METASTATIC	107	24 (22.4)	N.A. (16.13, N.A.)	81	45 (55.6)	3.91 (1.51, 7.69)	0.287 (0.173, 0.476) <0.0001	
UNRESECTABLE ADVANCED	18	5 (27.8)	N.A. (5.75, N.A.)	24	16 (66.7)	0.44 (0.13, 10.18)	0.220 (0.078, 0.618) 0.0019	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 139 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.3313
CURRENT/FORMER	136	33 (24.3)	N.A. (16.13, N.A.)	111	60 (54.1)	3.81 (0.53, 10.74)	0.291 (0.188, 0.449) <0.0001	
NEVER/UNKNOWN	22	3 (13.6)	N.A. (6.21, N.A.)	34	20 (58.8)	4.34 (0.49, 10.18)	0.140 (0.041, 0.476) 0.0003	
ALCOHOL USE								0.6891
CURRENT/FORMER	126	30 (23.8)	N.A. (16.13, N.A.)	117	64 (54.7)	3.81 (0.49, 10.74)	0.282 (0.181, 0.439) <0.0001	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (12.98, N.A.)	28	16 (57.1)	4.34 (0.92, N.A.)	0.225 (0.087, 0.580) 0.0008	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 140 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.3003
<= 1	80	21 (26.3)	N.A. (12.65, N.A.)	69	39 (56.5)	4.21 (1.05, 10.74)	0.327 (0.192, 0.558) <0.0001	
>= 2	78	15 (19.2)	N.A. (16.13, N.A.)	76	41 (53.9)	3.06 (0.26, N.A.)	0.218 (0.118, 0.402) <0.0001	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.6096
< 1 YEAR	128	32 (25.0)	N.A. (16.13, N.A.)	115	67 (58.3)	3.19 (0.99, 6.70)	0.275 (0.179, 0.423) <0.0001	
1 - < 3 YEARS	25	2 (8.0)	N.A. (7.13, N.A.)	21	7 (33.3)	10.74 (0.23, N.A.)	0.194 (0.040, 0.936) 0.0236	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 141 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4687
YES	38	6 (15.8)	N.A. (12.98, N.A.)	37	18 (48.6)	10.74 (0.20, N.A.)	0.205 (0.080, 0.528) 0.0003	
NO	120	30 (25.0)	N.A. (16.13, N.A.)	108	62 (57.4)	3.48 (1.05, 6.70)	0.287 (0.184, 0.448) <0.0001	
PRIOR RADIOTHERAPY								0.6134
YES	26	3 (11.5)	N.A.	27	11 (40.7)	10.74 (0.13, N.A.)	0.206 (0.057, 0.744) 0.0083	
NO	132	33 (25.0)	N.A. (12.98, N.A.)	118	69 (58.5)	3.06 (0.85, 6.70)	0.271 (0.177, 0.414) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 142 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.8633
< 10	53	10 (18.9)	N.A. (12.65, N.A.)	54	26 (48.1)	6.70 (1.05, N.A.)	0.284 (0.136, 0.591) 0.0004	
>= 10	92	23 (25.0)	N.A. (12.65, N.A.)	89	52 (58.4)	3.48 (0.23, 10.18)	0.290 (0.177, 0.476) <0.0001	
PD-L1 CPS II								0.7677
< 5	29	4 (13.8)	N.A. (5.75, N.A.)	24	8 (33.3)	N.A. (3.19, N.A.)	0.365 (0.110, 1.214) 0.0872	
>= 5	116	29 (25.0)	N.A. (12.98, N.A.)	119	70 (58.8)	2.79 (0.49, 6.70)	0.274 (0.177, 0.425) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 143 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.6861
< 10%	55	12 (21.8)	N.A. (7.62, N.A.)	57	29 (50.9)	5.32 (2.79, N.A.)	0.289 (0.146, 0.571) 0.0002	
>= 10%	103	24 (23.3)	N.A. (12.98, N.A.)	88	51 (58.0)	1.05 (0.20, 10.18)	0.252 (0.153, 0.414) <0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.4155
< 5%	38	9 (23.7)	N.A. (6.31, N.A.)	41	20 (48.8)	6.70 (2.79, N.A.)	0.342 (0.155, 0.756) 0.0056	
>= 5%	120	27 (22.5)	N.A. (16.13, N.A.)	104	60 (57.7)	1.94 (0.26, 7.69)	0.246 (0.154, 0.391) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 144 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	87 (55.1)	3.91 (2.79, 8.38)	145	44 (30.3)	N.A. (8.44, N.A.)	2.203 (1.528, 3.176) <0.0001	
AGE								0.8894
< 65	95	49 (51.6)	5.39 (3.25, 12.35)	75	18 (24.0)	N.A.	2.470 (1.434, 4.256) 0.0008	
>= 65 AND < 75	55	32 (58.2)	2.40 (1.38, 5.55)	58	22 (37.9)	8.44 (5.55, N.A.)	2.283 (1.320, 3.950) 0.0024	
>= 75	8	6 (75.0)	5.29 (0.10, N.A.)	12	4 (33.3)	N.A. (0.39, N.A.)	1.670 (0.437, 6.382) 0.4493	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 145 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5096
MALE	131	71 (54.2)	3.98 (2.66, 8.38)	122	35 (28.7)	N.A. (8.44, N.A.)	2.335 (1.552, 3.512) <0.0001	
FEMALE	27	16 (59.3)	3.02 (0.95, N.A.)	23	9 (39.1)	N.A. (1.87, N.A.)	1.646 (0.719, 3.764) 0.2352	
RACE								0.5794
ASIAN	117	72 (61.5)	3.02 (2.04, 5.29)	104	38 (36.5)	N.A. (5.78, N.A.)	2.126 (1.431, 3.156) 0.0001	
NON-ASIAN	41	15 (36.6)	17.05 (3.65, N.A.)	41	6 (14.6)	N.A.	2.638 (1.006, 6.919) 0.0407	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 146 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.2225
J/K/T	91	59 (64.8)	2.99 (1.87, 3.98)	85	36 (42.4)	8.44 (4.44, N.A.)	1.919 (1.264, 2.913) 0.0019	
REST OF ASIA	25	13 (52.0)	5.78 (0.79, N.A.)	19	2 (10.5)	N.A.	6.653 (1.496, 29.579) 0.0041	
REST OF WORLD	42	15 (35.7)	17.05 (3.65, N.A.)	41	6 (14.6)	N.A.	2.547 (0.972, 6.677) 0.0490	
REGION								0.6661
ASIA	116	72 (62.1)	2.99 (1.91, 5.29)	104	38 (36.5)	N.A. (5.78, N.A.)	2.171 (1.462, 3.224) <0.0001	
NON-ASIA	42	15 (35.7)	17.05 (3.65, N.A.)	41	6 (14.6)	N.A.	2.547 (0.972, 6.677) 0.0490	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 147 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9511
0	71	52 (73.2)	2.40 (1.41, 3.65)	69	28 (40.6)	8.44 (3.98, N.A.)	2.343 (1.478, 3.715) 0.0002	
1	87	35 (40.2)	15.74 (3.91, 23.36)	74	15 (20.3)	N.A.	2.281 (1.231, 4.226) 0.0071	
WEIGHT								0.3725
< 60 KG	96	51 (53.1)	5.78 (2.66, 12.35)	76	25 (32.9)	N.A. (7.36, N.A.)	1.808 (1.114, 2.935) 0.0150	
>= 60 KG	62	36 (58.1)	3.45 (1.41, 5.39)	69	19 (27.5)	N.A. (8.44, N.A.)	2.833 (1.619, 4.958) 0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 148 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.3547
STAGE I	5	4 (80.0)	3.81 (0.72, N.A.)	5	1 (20.0)	N.A. (0.89, N.A.)	4.192 (0.468, 37.566) 0.1636	
STAGE II	5	3 (60.0)	2.66 (0.10, N.A.)	5	0	N.E.	N.E. 0.0719	
STAGE III	33	17 (51.5)	12.35 (2.89, 17.05)	46	18 (39.1)	N.A. (3.98, N.A.)	1.177 (0.592, 2.341) 0.6431	
STAGE IV	114	62 (54.4)	3.45 (1.91, 5.78)	89	25 (28.1)	N.A. (8.44, N.A.)	2.589 (1.624, 4.127) <0.0001	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 149 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.1674
GX	11	4 (36.4)	N.A. (0.13, N.A.)	14	6 (42.9)	N.A. (1.08, N.A.)	1.200 (0.336, 4.280) 0.7783	
G1	8	6 (75.0)	2.66 (0.43, N.A.)	8	7 (87.5)	1.61 (0.07, N.A.)	0.757 (0.237, 2.420) 0.6380	
G2	58	32 (55.2)	5.39 (2.66, N.A.)	50	11 (22.0)	N.A. (7.36, N.A.)	3.139 (1.574, 6.260) 0.0006	
G3	28	16 (57.1)	3.65 (0.89, N.A.)	36	9 (25.0)	N.A.	2.675 (1.164, 6.152) 0.0160	
NOT OTHERWISE SPECIFIED	51	28 (54.9)	3.91 (1.64, 12.35)	37	11 (29.7)	8.44 (5.55, N.A.)	2.386 (1.184, 4.811) 0.0121	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 150 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8355
UPPER THORACIC	37	18 (48.6)	12.35 (1.87, N.A.)	25	8 (32.0)	N.A. (2.23, N.A.)	1.596 (0.687, 3.707) 0.2726	
MIDDLE THORACIC	50	29 (58.0)	3.32 (1.61, 3.98)	52	17 (32.7)	N.A. (5.75, N.A.)	2.639 (1.440, 4.836) 0.0011	
LOWER THORACIC	59	36 (61.0)	3.65 (1.64, 5.95)	60	18 (30.0)	N.A. (8.44, N.A.)	2.540 (1.432, 4.507) 0.0010	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	N.A. (5.39, N.A.)	8	1 (12.5)	N.A. (1.08, N.A.)	1.259 (0.114, 13.929) 0.8507	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 151 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.6719
RECURRENT - LOCO-REGIONAL	8	3 (37.5)	11.99 (3.65, N.A.)	13	4 (30.8)	N.A. (0.89, N.A.)	1.020 (0.224, 4.653) 0.9796	
RECURRENT - DISTANT	25	14 (56.0)	5.95 (1.87, 15.74)	27	9 (33.3)	N.A. (3.98, N.A.)	1.551 (0.641, 3.754) 0.3273	
DE NOVO METASTATIC	107	57 (53.3)	3.65 (1.91, 5.78)	81	23 (28.4)	N.A. (8.44, N.A.)	2.523 (1.552, 4.103) 0.0001	
UNRESECTABLE ADVANCED	18	13 (72.2)	2.40 (0.89, 17.05)	24	8 (33.3)	N.A. (3.22, N.A.)	2.643 (1.069, 6.537) 0.0291	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 152 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6315
CURRENT/FORMER	136	78 (57.4)	3.81 (2.40, 5.78)	111	35 (31.5)	N.A. (8.44, N.A.)	2.260 (1.512, 3.378) <0.0001	
NEVER/UNKNOWN	22	9 (40.9)	17.05 (1.38, N.A.)	34	9 (26.5)	N.A. (5.78, N.A.)	1.650 (0.636, 4.282) 0.2982	
ALCOHOL USE								0.8826
CURRENT/FORMER	126	72 (57.1)	3.65 (2.40, 5.95)	117	37 (31.6)	N.A. (8.44, N.A.)	2.203 (1.477, 3.286) <0.0001	
NEVER/UNKNOWN	32	15 (46.9)	17.05 (0.72, N.A.)	28	7 (25.0)	N.A.	2.308 (0.929, 5.729) 0.0639	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 153 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.6558
<= 1	80	46 (57.5)	3.98 (2.23, 11.99)	69	24 (34.8)	N.A. (5.78, N.A.)	2.084 (1.271, 3.416) 0.0029	
>= 2	78	41 (52.6)	3.91 (2.20, 17.05)	76	20 (26.3)	N.A.	2.395 (1.390, 4.126) 0.0012	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3588
< 1 YEAR	128	73 (57.0)	3.45 (2.04, 5.55)	115	35 (30.4)	N.A. (8.44, N.A.)	2.394 (1.594, 3.596) <0.0001	
1 - < 3 YEARS	25	10 (40.0)	12.35 (5.39, N.A.)	21	6 (28.6)	N.A. (1.91, N.A.)	1.341 (0.486, 3.702) 0.5666	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 154 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.3557
YES	38	20 (52.6)	5.95 (2.79, N.A.)	37	12 (32.4)	N.A. (4.04, N.A.)	1.550 (0.751, 3.199) 0.2310	
NO	120	67 (55.8)	3.45 (2.20, 5.78)	108	32 (29.6)	N.A. (8.44, N.A.)	2.498 (1.633, 3.821) <0.0001	
PRIOR RADIOTHERAPY								0.9768
YES	26	12 (46.2)	11.99 (2.79, N.A.)	27	6 (22.2)	N.A.	1.956 (0.722, 5.301) 0.1788	
NO	132	75 (56.8)	3.65 (2.20, 5.55)	118	38 (32.2)	N.A. (8.44, N.A.)	2.244 (1.514, 3.326) <0.0001	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 155 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.0717
< 10	53	30 (56.6)	3.91 (2.20, 11.99)	54	11 (20.4)	N.A. (7.36, N.A.)	3.167 (1.569, 6.393) 0.0007	
>= 10	92	47 (51.1)	5.55 (2.99, 15.74)	89	33 (37.1)	N.A. (5.75, N.A.)	1.589 (1.015, 2.488) 0.0409	
PD-L1 CPS II								0.1609
< 5	29	16 (55.2)	3.65 (1.64, N.A.)	24	4 (16.7)	N.A.	4.325 (1.421, 13.162) 0.0048	
>= 5	116	61 (52.6)	5.39 (3.02, 12.12)	119	40 (33.6)	N.A. (7.36, N.A.)	1.795 (1.202, 2.682) 0.0038	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 156 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.0037*
< 10%	55	34 (61.8)	3.65 (2.14, 8.38)	57	8 (14.0)	N.A.	5.550 (2.552, 12.073) <0.0001	
>= 10%	103	53 (51.5)	5.39 (2.40, 15.74)	88	36 (40.9)	8.44 (5.75, N.A.)	1.489 (0.971, 2.284) 0.0664	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.0051*
< 5%	38	24 (63.2)	2.99 (1.41, 8.38)	41	5 (12.2)	N.A.	7.137 (2.710, 18.797) <0.0001	
>= 5%	120	63 (52.5)	5.39 (2.66, 12.35)	104	39 (37.5)	N.A. (5.78, N.A.)	1.601 (1.068, 2.400) 0.0216	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 157 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI) (mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	42 (26.6)	N.A.	145	10 (6.9)	N.A.	4.457 (2.233, 8.897) <0.0001	
AGE								0.9786
< 65	95	25 (26.3)	N.A. (14.29, N.A.)	75	6 (8.0)	N.A.	3.751 (1.536, 9.162) 0.0018	
>= 65 AND < 75	55	14 (25.5)	N.A.	58	4 (6.9)	N.A.	4.476 (1.471, 13.619) 0.0038	
>= 75	8	3 (37.5)	N.A. (0.72, N.A.)	12	0	N.E.	N.E. 0.0249	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 158 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7921
MALE	131	36 (27.5)	N.A. (14.29, N.A.)	122	9 (7.4)	N.A.	4.321 (2.076, 8.991) <0.0001	
FEMALE	27	6 (22.2)	N.A.	23	1 (4.3)	N.A.	5.781 (0.695, 48.051) 0.0658	
RACE								0.9864
ASIAN	117	38 (32.5)	N.A. (9.23, N.A.)	104	10 (9.6)	N.A.	4.072 (2.027, 8.182) <0.0001	
NON-ASIAN	41	4 (9.8)	N.A. (14.29, N.A.)	41	0	N.E.	N.E. 0.0569	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 159 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.5526
J/K/T	91	27 (29.7)	N.A.	85	9 (10.6)	N.A.	3.402 (1.598, 7.242) 0.0007	
REST OF ASIA	25	11 (44.0)	9.23 (0.92, N.A.)	19	1 (5.3)	N.A.	10.441 (1.347, 80.963) 0.0052	
REST OF WORLD	42	4 (9.5)	N.A. (14.29, N.A.)	41	0	N.E.	N.E. 0.0601	
REGION								0.9865
ASIA	116	38 (32.8)	N.A. (9.23, N.A.)	104	10 (9.6)	N.A.	4.129 (2.055, 8.296) <0.0001	
NON-ASIA	42	4 (9.5)	N.A. (14.29, N.A.)	41	0	N.E.	N.E. 0.0601	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 160 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9872
0	71	25 (35.2)	N.A. (6.34, N.A.)	69	10 (14.5)	N.A.	2.851 (1.369, 5.940) 0.0034	
1	87	17 (19.5)	N.A.	74	0	N.E.	N.E. <0.0001	
WEIGHT								0.9726
< 60 KG	96	24 (25.0)	N.A.	76	5 (6.6)	N.A.	4.492 (1.713, 11.780) 0.0008	
>= 60 KG	62	18 (29.0)	N.A. (9.23, N.A.)	69	5 (7.2)	N.A.	4.441 (1.638, 12.039) 0.0014	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 161 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.2462
STAGE I	5	2 (40.0)	N.A. (0.72, N.A.)	5	0	N.E.	N.E. 0.1343	
STAGE II	5	2 (40.0)	N.A. (1.81, N.A.)	5	0	N.E.	N.E. 0.2457	
STAGE III	33	4 (12.1)	N.A.	46	5 (10.9)	N.A.	1.220 (0.327, 4.557) 0.7668	
STAGE IV	114	33 (28.9)	N.A. (14.29, N.A.)	89	5 (5.6)	N.A.	5.977 (2.328, 15.345) <0.0001	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 162 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9533
GX	11	2 (18.2)	N.A. (0.23, N.A.)	14	1 (7.1)	N.A.	3.252 (0.289, 36.576) 0.3133	
G1	8	3 (37.5)	N.A. (0.72, N.A.)	8	1 (12.5)	N.A. (2.04, N.A.)	3.875 (0.399, 37.609) 0.2088	
G2	58	14 (24.1)	N.A.	50	3 (6.0)	N.A.	4.296 (1.233, 14.969) 0.0126	
G3	28	10 (35.7)	N.A. (2.79, N.A.)	36	4 (11.1)	N.A.	4.264 (1.333, 13.639) 0.0078	
NOT OTHERWISE SPECIFIED	51	12 (23.5)	N.A. (14.29, N.A.)	37	1 (2.7)	N.A.	9.913 (1.284, 76.562) 0.0068	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 163 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7136
UPPER THORACIC	37	8 (21.6)	N.A.	25	2 (8.0)	N.A.	2.797 (0.593, 13.187) 0.1746	
MIDDLE THORACIC	50	14 (28.0)	N.A. (14.29, N.A.)	52	5 (9.6)	N.A.	3.543 (1.268, 9.899) 0.0102	
LOWER THORACIC	59	19 (32.2)	N.A. (9.23, N.A.)	60	3 (5.0)	N.A.	7.809 (2.306, 26.441) <0.0001	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 164 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.3820
RECURRENT - LOCO-REGIONAL	8	1 (12.5)	N.A. (3.65, N.A.)	13	0	N.E.	N.E. 0.2100	
RECURRENT - DISTANT	25	6 (24.0)	N.A.	27	1 (3.7)	N.A.	7.241 (0.872, 60.163) 0.0318	
DE NOVO METASTATIC	107	31 (29.0)	N.A. (14.29, N.A.)	81	5 (6.2)	N.A.	5.423 (2.103, 13.986) <0.0001	
UNRESECTABLE ADVANCED	18	4 (22.2)	N.A.	24	4 (16.7)	N.A. (7.36, N.A.)	1.459 (0.364, 5.851) 0.5914	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 165 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6377
CURRENT/FORMER	136	38 (27.9)	N.A.	111	9 (8.1)	N.A.	4.102 (1.981, 8.490) <0.0001	
NEVER/UNKNOWN	22	4 (18.2)	N.A. (14.29, N.A.)	34	1 (2.9)	N.A.	5.325 (0.574, 49.371) 0.1030	
ALCOHOL USE								0.3280
CURRENT/FORMER	126	32 (25.4)	N.A. (14.29, N.A.)	117	9 (7.7)	N.A.	3.710 (1.768, 7.788) 0.0002	
NEVER/UNKNOWN	32	10 (31.3)	N.A. (5.78, N.A.)	28	1 (3.6)	N.A.	11.128 (1.421, 87.135) 0.0039	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 166 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.7073
<= 1	80	23 (28.8)	N.A. (9.23, N.A.)	69	6 (8.7)	N.A.	3.963 (1.612, 9.742) 0.0012	
>= 2	78	19 (24.4)	N.A. (14.29, N.A.)	76	4 (5.3)	N.A.	5.168 (1.749, 15.268) 0.0009	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9897
< 1 YEAR	128	36 (28.1)	N.A. (14.29, N.A.)	115	10 (8.7)	N.A.	3.721 (1.841, 7.521) <0.0001	
1 - < 3 YEARS	25	3 (12.0)	N.A.	21	0	N.E.	N.E. 0.1176	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 167 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.5319
YES	38	8 (21.1)	N.A.	37	1 (2.7)	N.A.	8.297 (1.038, 66.348) 0.0169	
NO	120	34 (28.3)	N.A. (14.29, N.A.)	108	9 (8.3)	N.A.	3.998 (1.912, 8.362) <0.0001	
PRIOR RADIOTHERAPY								0.9875
YES	26	6 (23.1)	N.A. (3.65, N.A.)	27	0	N.E.	N.E. 0.0067	
NO	132	36 (27.3)	N.A. (14.29, N.A.)	118	10 (8.5)	N.A.	3.691 (1.827, 7.454) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 168 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.8508
< 10	53	12 (22.6)	N.A.	54	3 (5.6)	N.A.	4.538 (1.278, 16.108) 0.0103	
>= 10	92	24 (26.1)	N.A. (14.29, N.A.)	89	7 (7.9)	N.A.	3.768 (1.619, 8.771) 0.0010	
PD-L1 CPS II								0.9888
< 5	29	6 (20.7)	N.A.	24	0	N.E.	N.E. 0.0138	
>= 5	116	30 (25.9)	N.A. (14.29, N.A.)	119	10 (8.4)	N.A.	3.436 (1.676, 7.046) 0.0003	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 169 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3097
< 10%	55	15 (27.3)	N.A. (9.23, N.A.)	57	2 (3.5)	N.A.	8.230 (1.877, 36.093) 0.0009	
>= 10%	103	27 (26.2)	N.A. (14.29, N.A.)	88	8 (9.1)	N.A.	3.443 (1.560, 7.598) 0.0011	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.1855
< 5%	38	12 (31.6)	N.A. (3.98, N.A.)	41	1 (2.4)	N.A.	14.641 (1.902,>99.999) 0.0006	
>= 5%	120	30 (25.0)	N.A.	104	9 (8.7)	N.A.	3.301 (1.563, 6.970) 0.0009	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 170 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	35 (22.2)	N.A. (21.19, N.A.)	145	7 (4.8)	N.A.	4.906 (2.167, 11.106) <0.0001	
AGE								0.8919
< 65	95	16 (16.8)	N.A. (17.05, N.A.)	75	2 (2.7)	N.A.	6.777 (1.551, 29.607) 0.0033	
>= 65 AND < 75	55	16 (29.1)	21.19 (21.19, N.A.)	58	4 (6.9)	N.A. (8.44, N.A.)	4.670 (1.547, 14.094) 0.0026	
>= 75	8	3 (37.5)	N.A. (0.10, N.A.)	12	1 (8.3)	N.A. (6.05, N.A.)	4.438 (0.460, 42.795) 0.1585	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 171 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9896
MALE	131	26 (19.8)	N.A.	122	7 (5.7)	N.A.	3.819 (1.652, 8.825) 0.0008	
FEMALE	27	9 (33.3)	21.19 (5.65, N.A.)	23	0	N.E.	N.E. 0.0089	
RACE								0.6837
ASIAN	117	28 (23.9)	N.A. (21.19, N.A.)	104	6 (5.8)	N.A.	4.488 (1.849, 10.896) 0.0003	
NON-ASIAN	41	7 (17.1)	N.A. (17.05, N.A.)	41	1 (2.4)	N.A.	7.378 (0.894, 60.870) 0.0305	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9287
J/K/T	91	25 (27.5)	21.19 (11.96, N.A.)	85	6 (7.1)	N.A.	4.454 (1.815, 10.930) 0.0004	
REST OF ASIA	25	3 (12.0)	N.A.	19	0	N.E.	N.E. 0.1393	
REST OF WORLD	42	7 (16.7)	N.A. (17.05, N.A.)	41	1 (2.4)	N.A.	7.151 (0.867, 58.980) 0.0339	
REGION								0.7183
ASIA	116	28 (24.1)	N.A. (11.99, N.A.)	104	6 (5.8)	N.A.	4.561 (1.879, 11.072) 0.0002	
NON-ASIA	42	7 (16.7)	N.A. (17.05, N.A.)	41	1 (2.4)	N.A.	7.151 (0.867, 58.980) 0.0339	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 173 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7420
0	71	21 (29.6)	N.A. (21.19, N.A.)	69	4 (5.8)	N.A.	5.601 (1.913, 16.398) 0.0004	
1	87	14 (16.1)	N.A. (17.05, N.A.)	74	3 (4.1)	N.A.	3.949 (1.116, 13.976) 0.0218	
WEIGHT								0.2490
< 60 KG	96	25 (26.0)	21.19 (11.99, N.A.)	76	3 (3.9)	N.A.	6.919 (2.073, 23.098) 0.0003	
>= 60 KG	62	10 (16.1)	N.A.	69	4 (5.8)	N.A.	3.093 (0.968, 9.886) 0.0452	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 174 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9830
STAGE I	5	1 (20.0)	N.A. (11.99, N.A.)	5	0	N.E.	N.E. 0.4795	
STAGE II	5	2 (40.0)	N.A. (0.10, N.A.)	5	0	N.E.	N.E. 0.1343	
STAGE III	33	8 (24.2)	N.A. (17.05, N.A.)	46	2 (4.3)	N.A.	5.545 (1.161, 26.482) 0.0162	
STAGE IV	114	23 (20.2)	N.A. (21.19, N.A.)	89	5 (5.6)	N.A.	4.004 (1.513, 10.600) 0.0025	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 175 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.4791
GX	11	1 (9.1)	N.A. (21.19, N.A.)	14	0	N.E.	N.E. N.A.	
G1	8	3 (37.5)	N.A. (0.43, N.A.)	8	2 (25.0)	N.A. (0.99, N.A.)	0.962 (0.135, 6.872) 0.9695	
G2	58	14 (24.1)	N.A.	50	1 (2.0)	N.A.	14.661 (1.925,>99.999) 0.0006	
G3	28	6 (21.4)	N.A. (17.05, N.A.)	36	0	N.E.	N.E. 0.0063	
NOT OTHERWISE SPECIFIED	51	10 (19.6)	N.A. (11.99, N.A.)	37	4 (10.8)	N.A. (8.44, N.A.)	1.747 (0.542, 5.634) 0.3439	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 176 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								>0.9999
UPPER THORACIC	37	8 (21.6)	17.05 (N.A., N.A.)	25	0	N.E.	N.E. 0.0107	
MIDDLE THORACIC	50	10 (20.0)	N.A.	52	3 (5.8)	N.A.	4.250 (1.165, 15.508) 0.0172	
LOWER THORACIC	59	15 (25.4)	N.A. (11.96, N.A.)	60	4 (6.7)	N.A.	3.850 (1.259, 11.774) 0.0111	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (11.99, N.A.)	8	0	N.E.	N.E. N.A.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 177 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9971
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	11.99 (3.65, N.A.)	13	0	N.E.	N.E. 0.0797	
RECURRENT - DISTANT	25	5 (20.0)	N.A. (5.95, N.A.)	27	2 (7.4)	N.A.	2.980 (0.578, 15.368) 0.1707	
DE NOVO METASTATIC	107	21 (19.6)	N.A. (21.19, N.A.)	81	5 (6.2)	N.A.	3.451 (1.291, 9.220) 0.0086	
UNRESECTABLE ADVANCED	18	7 (38.9)	17.05 (2.89, N.A.)	24	0	N.E.	N.E. 0.0023	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 178 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6440
CURRENT/FORMER	136	30 (22.1)	N.A.	111	6 (5.4)	N.A.	4.573 (1.898, 11.015) 0.0002	
NEVER/UNKNOWN	22	5 (22.7)	21.19 (17.05, N.A.)	34	1 (2.9)	N.A.	5.643 (0.603, 52.804) 0.0911	
ALCOHOL USE								0.9888
CURRENT/FORMER	126	28 (22.2)	N.A.	117	7 (6.0)	N.A.	4.206 (1.832, 9.656) 0.0002	
NEVER/UNKNOWN	32	7 (21.9)	21.19 (17.05, N.A.)	28	0	N.E.	N.E. 0.0265	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 179 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.0654
<= 1	80	16 (20.0)	N.A.	69	6 (8.7)	N.A.	2.534 (0.989, 6.489) 0.0448	
>= 2	78	19 (24.4)	21.19 (11.96, N.A.)	76	1 (1.3)	N.A.	19.285 (2.563,>99.999) <0.0001	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.5225
< 1 YEAR	128	28 (21.9)	N.A. (21.19, N.A.)	115	5 (4.3)	N.A.	5.337 (2.046, 13.920) 0.0001	
1 - < 3 YEARS	25	6 (24.0)	N.A. (5.95, N.A.)	21	2 (9.5)	N.A.	2.995 (0.601, 14.921) 0.1599	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 180 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.8750
YES	38	9 (23.7)	N.A. (11.96, N.A.)	37	2 (5.4)	N.A.	4.005 (0.857, 18.723) 0.0571	
NO	120	26 (21.7)	N.A. (21.19, N.A.)	108	5 (4.6)	N.A.	5.256 (2.004, 13.788) 0.0002	
PRIOR RADIOTHERAPY								0.9890
YES	26	7 (26.9)	11.99 (5.95, N.A.)	27	0	N.E.	N.E. 0.0056	
NO	132	28 (21.2)	N.A. (21.19, N.A.)	118	7 (5.9)	N.A.	3.782 (1.639, 8.726) 0.0008	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 181 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.2697
< 10	53	15 (28.3)	11.99 (11.96, N.A.)	54	2 (3.7)	N.A.	8.583 (1.951, 37.750) 0.0007	
>= 10	92	16 (17.4)	N.A. (21.19, N.A.)	89	5 (5.6)	N.A.	3.060 (1.103, 8.488) 0.0239	
PD-L1 CPS II								0.9034
< 5	29	6 (20.7)	N.A.	24	1 (4.2)	N.A.	5.831 (0.701, 48.498) 0.0643	
>= 5	116	25 (21.6)	N.A. (17.05, N.A.)	119	6 (5.0)	N.A.	4.289 (1.744, 10.549) 0.0006	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 182 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3080
< 10%	55	12 (21.8)	N.A. (11.96, N.A.)	57	1 (1.8)	N.A.	12.609 (1.635, 97.250) 0.0018	
>= 10%	103	23 (22.3)	N.A. (17.05, N.A.)	88	6 (6.8)	N.A.	3.548 (1.429, 8.812) 0.0036	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.6638
< 5%	38	7 (18.4)	N.A. (11.96, N.A.)	41	1 (2.4)	N.A.	7.473 (0.914, 61.085) 0.0277	
>= 5%	120	28 (23.3)	N.A. (17.05, N.A.)	104	6 (5.8)	N.A.	4.424 (1.817, 10.771) 0.0003	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 183 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	10 (6.3)	N.A.	145	2 (1.4)	N.A.	4.831 (1.058, 22.054) 0.0245	
AGE								N.M.E.
< 65	95	4 (4.2)	N.M.E.	75	2 (2.7)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	6 (10.9)	N.M.E.	58	0	N.M.E.	N.M.E.	
>= 75	8	0	N.M.E.	12	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 184 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	131	8 (6.1)	N.M.E.	122	1 (0.8)	N.M.E.	N.M.E.	
FEMALE	27	2 (7.4)	N.M.E.	23	1 (4.3)	N.M.E.	N.M.E.	
RACE								N.M.E.
ASIAN	117	7 (6.0)	N.M.E.	104	1 (1.0)	N.M.E.	N.M.E.	
NON-ASIAN	41	3 (7.3)	N.M.E.	41	1 (2.4)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 185 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	6 (6.6)	N.M.E.	85	1 (1.2)	N.M.E.	N.M.E.	
REST OF ASIA	25	1 (4.0)	N.M.E.	19	0	N.M.E.	N.M.E.	
REST OF WORLD	42	3 (7.1)	N.M.E.	41	1 (2.4)	N.M.E.	N.M.E.	
REGION								N.M.E.
ASIA	116	7 (6.0)	N.M.E.	104	1 (1.0)	N.M.E.	N.M.E.	
NON-ASIA	42	3 (7.1)	N.M.E.	41	1 (2.4)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 186 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	5 (7.0)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
1	87	5 (5.7)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	4 (4.2)	N.M.E.	76	0	N.M.E.	N.M.E.	
>= 60 KG	62	6 (9.7)	N.M.E.	69	2 (2.9)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 187 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	1 (3.0)	N.A.	46	0	N.E.	N.E. 0.2288	
STAGE IV	114	9 (7.9)	N.A.	89	2 (2.2)	N.A.	3.809 (0.822, 17.643) 0.0659	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 188 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
G2	58	4 (6.9)	N.M.E.	50	0	N.M.E.	N.M.E.	
G3	28	3 (10.7)	N.M.E.	36	0	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	3 (5.9)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 189 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	4 (10.8)	N.M.E.	25	0	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	2 (4.0)	N.M.E.	52	1 (1.9)	N.M.E.	N.M.E.	
LOWER THORACIC	59	4 (6.8)	N.M.E.	60	1 (1.7)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	0	N.M.E.	8	0	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 190 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	0	N.E.	N.E. N.E.	
RECURRENT - DISTANT	25	0	N.E.	27	0	N.E.	N.E. N.E.	
DE NOVO METASTATIC	107	9 (8.4)	N.A.	81	2 (2.5)	N.A.	3.704 (0.800, 17.162) 0.0726	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A.	24	0	N.E.	N.E. 0.2553	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 191 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9932
CURRENT/FORMER	136	8 (5.9)	N.A.	111	2 (1.8)	N.A.	3.406 (0.723, 16.043) 0.0994	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	0	N.E.	N.E. 0.0652	
ALCOHOL USE								0.9943
CURRENT/FORMER	126	9 (7.1)	N.A.	117	2 (1.7)	N.A.	4.394 (0.949, 20.341) 0.0385	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	0	N.E.	N.E. 0.3496	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 192 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	5 (6.3)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
>= 2	78	5 (6.4)	N.M.E.	76	1 (1.3)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9996
< 1 YEAR	128	10 (7.8)	N.A.	115	2 (1.7)	N.A.	4.804 (1.052, 21.941) 0.0252	
1 - < 3 YEARS	25	0	N.E.	21	0	N.E.	N.E. N.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 193 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9995
YES	38	0	N.E.	37	0	N.E.	N.E. N.E.	
NO	120	10 (8.3)	N.A.	108	2 (1.9)	N.A.	4.905 (1.074, 22.402) 0.0230	
PRIOR RADIOTHERAPY								0.9996
YES	26	0	N.E.	27	0	N.E.	N.E. N.E.	
NO	132	10 (7.6)	N.A.	118	2 (1.7)	N.A.	4.760 (1.042, 21.734) 0.0262	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 194 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	4 (7.5)	N.M.E.	54	0	N.M.E.	N.M.E.	
>= 10	92	6 (6.5)	N.M.E.	89	2 (2.2)	N.M.E.	N.M.E.	
PD-L1 CPS II								N.M.E.
< 5	29	3 (10.3)	N.M.E.	24	0	N.M.E.	N.M.E.	
>= 5	116	7 (6.0)	N.M.E.	119	2 (1.7)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 195 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	7 (12.7)	N.M.E.	57	0	N.M.E.	N.M.E.	
>= 10%	103	3 (2.9)	N.M.E.	88	2 (2.3)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								N.M.E.
< 5%	38	4 (10.5)	N.M.E.	41	0	N.M.E.	N.M.E.	
>= 5%	120	6 (5.0)	N.M.E.	104	2 (1.9)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 196 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	8 (5.1)	N.A.	145	21 (14.5)	N.A.	0.240 (0.097, 0.598) 0.0009	
AGE								0.3636
< 65	95	6 (6.3)	N.A. (23.36, N.A.)	75	7 (9.3)	N.A.	0.434 (0.127, 1.486) 0.1712	
>= 65 AND < 75	55	2 (3.6)	N.A.	58	12 (20.7)	N.A.	0.161 (0.036, 0.719) 0.0062	
>= 75	8	0	N.E.	12	2 (16.7)	N.A. (0.82, N.A.)	N.E. 0.2378	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 197 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8068
MALE	131	6 (4.6)	N.A. (23.46, N.A.)	122	17 (13.9)	N.A.	0.202 (0.067, 0.605) 0.0016	
FEMALE	27	2 (7.4)	N.A.	23	4 (17.4)	N.A.	0.372 (0.068, 2.033) 0.2347	
RACE								0.4192
ASIAN	117	7 (6.0)	N.A.	104	20 (19.2)	N.A.	0.234 (0.094, 0.585) 0.0007	
NON-ASIAN	41	1 (2.4)	N.A. (23.36, N.A.)	41	1 (2.4)	N.A.	<0.001 (<0.001, N.A.) 0.3357	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 198 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.6606
J/K/T	91	6 (6.6)	N.A. (23.46, N.A.)	85	20 (23.5)	N.A.	0.202 (0.076, 0.542) 0.0004	
REST OF ASIA	25	1 (4.0)	N.A.	19	0	N.E.	N.E. 0.4193	
REST OF WORLD	42	1 (2.4)	N.A. (23.36, N.A.)	41	1 (2.4)	N.A.	<0.001 (<0.001, N.A.) 0.3294	
REGION								0.4319
ASIA	116	7 (6.0)	N.A.	104	20 (19.2)	N.A.	0.237 (0.095, 0.592) 0.0008	
NON-ASIA	42	1 (2.4)	N.A. (23.36, N.A.)	41	1 (2.4)	N.A.	<0.001 (<0.001, N.A.) 0.3294	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 199 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.4840
0	71	7 (9.9)	N.A. (23.46, N.A.)	69	16 (23.2)	N.A.	0.299 (0.117, 0.765) 0.0076	
1	87	1 (1.1)	N.A. (23.36, N.A.)	74	5 (6.8)	N.A.	<0.001 (<0.001, N.A.) 0.0210	
WEIGHT								0.1629
< 60 KG	96	4 (4.2)	N.A. (23.36, N.A.)	76	15 (19.7)	N.A.	0.097 (0.022, 0.425) 0.0001	
>= 60 KG	62	4 (6.5)	N.A.	69	6 (8.7)	N.A.	0.674 (0.186, 2.435) 0.5446	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 200 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8308
STAGE I	5	1 (20.0)	N.A. (3.81, N.A.)	5	1 (20.0)	N.A. (0.89, N.A.)	0.775 (0.047, 12.667) 0.8575	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	2 (6.1)	N.A. (23.36, N.A.)	46	9 (19.6)	N.A.	<0.001 (<0.001, N.A.) 0.0089	
STAGE IV	114	5 (4.4)	N.A.	89	11 (12.4)	N.A.	0.330 (0.114, 0.956) 0.0320	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 201 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9418
GX	11	0	N.E.	14	5 (35.7)	N.A. (1.08, N.A.)	N.E. 0.0581	
G1	8	0	N.E.	8	4 (50.0)	N.A. (0.92, N.A.)	N.E. 0.0338	
G2	58	3 (5.2)	N.A. (23.36, N.A.)	50	3 (6.0)	N.A.	0.273 (0.028, 2.631) 0.2291	
G3	28	1 (3.6)	N.A. (12.12, N.A.)	36	1 (2.8)	N.A.	0.734 (0.040, 13.341) 0.8338	
NOT OTHERWISE SPECIFIED	51	4 (7.8)	N.A.	37	8 (21.6)	N.A.	0.325 (0.097, 1.084) 0.0547	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 202 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8108
UPPER THORACIC	37	1 (2.7)	N.A.	25	4 (16.0)	N.A.	0.138 (0.015, 1.254) 0.0410	
MIDDLE THORACIC	50	4 (8.0)	N.A.	52	8 (15.4)	N.A.	0.519 (0.156, 1.725) 0.2761	
LOWER THORACIC	59	3 (5.1)	N.A. (23.36, N.A.)	60	8 (13.3)	N.A.	0.090 (0.011, 0.777) 0.0085	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	1 (12.5)	N.A. (1.08, N.A.)	N.E. 0.2100	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 203 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9351
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	3 (23.1)	N.A.	N.E.	
						(0.89, N.A.)	0.1436	
RECURRENT - DISTANT	25	3 (12.0)	23.46	27	5 (18.5)	N.A.	0.210	
			(23.36, N.A.)				(0.025, 1.802)	
							0.1163	
DE NOVO METASTATIC	107	4 (3.7)	N.A.	81	9 (11.1)	N.A.	0.337	
							(0.104, 1.096)	
							0.0579	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A.	24	4 (16.7)	N.A.	0.259	
			(12.12, N.A.)				(0.028, 2.359)	
							0.1982	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 204 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.8276
CURRENT/FORMER	136	7 (5.1)	N.A. (23.46, N.A.)	111	18 (16.2)	N.A.	0.203 (0.075, 0.551) 0.0005	
NEVER/UNKNOWN	22	1 (4.5)	N.A.	34	3 (8.8)	N.A.	0.506 (0.052, 4.912) 0.5497	
ALCOHOL USE								0.7954
CURRENT/FORMER	126	7 (5.6)	N.A. (23.46, N.A.)	117	19 (16.2)	N.A.	0.219 (0.081, 0.591) 0.0010	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	2 (7.1)	N.A.	0.397 (0.036, 4.405) 0.4359	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 205 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.7284
<= 1	80	5 (6.3)	N.A. (23.46, N.A.)	69	14 (20.3)	N.A.	0.221 (0.072, 0.672) 0.0036	
>= 2	78	3 (3.8)	N.A. (23.36, N.A.)	76	7 (9.2)	N.A.	0.271 (0.056, 1.305) 0.0809	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.6696
< 1 YEAR	128	7 (5.5)	N.A.	115	16 (13.9)	N.A.	0.309 (0.120, 0.796) 0.0102	
1 - < 3 YEARS	25	1 (4.0)	N.A. (23.46, N.A.)	21	3 (14.3)	N.A.	<0.001 (<0.001, N.A.) 0.0454	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 206 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9228
YES	38	3 (7.9)	23.46 (23.36, N.A.)	37	8 (21.6)	N.A.	0.109 (0.014, 0.869) 0.0108	
NO	120	5 (4.2)	N.A.	108	13 (12.0)	N.A.	0.320 (0.113, 0.904) 0.0236	
PRIOR RADIOTHERAPY								0.4305
YES	26	2 (7.7)	23.46 (23.36, N.A.)	27	3 (11.1)	N.A.	<0.001 (<0.001, N.A.) 0.0873	
NO	132	6 (4.5)	N.A.	118	18 (15.3)	N.A.	0.272 (0.107, 0.688) 0.0033	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 207 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.4634
< 10	53	2 (3.8)	N.A. (23.36, N.A.)	54	4 (7.4)	N.A.	0.258 (0.029, 2.309) 0.1915	
>= 10	92	5 (5.4)	N.A. (23.46, N.A.)	89	17 (19.1)	N.A.	0.206 (0.069, 0.615) 0.0018	
PD-L1 CPS II								0.1393
< 5	29	2 (6.9)	N.A. (23.36, N.A.)	24	1 (4.2)	N.A.	0.913 (0.057, 14.635) 0.9486	
>= 5	116	5 (4.3)	N.A.	119	20 (16.8)	N.A.	0.186 (0.063, 0.545) 0.0006	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 208 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.0924
< 10%	55	3 (5.5)	N.A. (23.36, N.A.)	57	3 (5.3)	N.A.	0.641 (0.106, 3.853) 0.6238	
>= 10%	103	5 (4.9)	N.A.	88	18 (20.5)	N.A.	0.172 (0.058, 0.511) 0.0003	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.1895
< 5%	38	2 (5.3)	N.A.	41	2 (4.9)	N.A.	1.013 (0.143, 7.197) 0.9898	
>= 5%	120	6 (5.0)	N.A. (23.46, N.A.)	104	19 (18.3)	N.A.	0.165 (0.056, 0.489) 0.0002	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 209 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	31 (19.6)	N.A.	145	4 (2.8)	N.A.	7.186 (2.529, 20.421) <0.0001	
AGE								0.8614
< 65	95	20 (21.1)	N.A. (12.32, N.A.)	75	3 (4.0)	N.A.	5.358 (1.588, 18.078) 0.0024	
>= 65 AND < 75	55	10 (18.2)	N.A.	58	1 (1.7)	N.A.	11.567 (1.480, 90.398) 0.0031	
>= 75	8	1 (12.5)	N.A. (0.95, N.A.)	12	0	N.E.	N.E. 0.2410	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 210 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2112
MALE	131	29 (22.1)	N.A.	122	3 (2.5)	N.A.	9.322 (2.832, 30.691) <0.0001	
FEMALE	27	2 (7.4)	N.A.	23	1 (4.3)	N.A. (10.15, N.A.)	1.818 (0.165, 20.075) 0.6205	
RACE								0.6976
ASIAN	117	26 (22.2)	N.A. (12.98, N.A.)	104	3 (2.9)	N.A.	7.847 (2.368, 25.999) <0.0001	
NON-ASIAN	41	5 (12.2)	N.A.	41	1 (2.4)	N.A. (10.15, N.A.)	4.477 (0.513, 39.066) 0.1392	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 211 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9999
J/K/T	91	18 (19.8)	N.A.	85	3 (3.5)	N.A.	5.755 (1.690, 19.599) 0.0015	
REST OF ASIA	25	7 (28.0)	12.98 (3.58, N.A.)	19	0	N.E.	N.E. 0.0278	
REST OF WORLD	42	6 (14.3)	N.A.	41	1 (2.4)	N.A. (10.15, N.A.)	5.495 (0.653, 46.273) 0.0793	
REGION								0.8250
ASIA	116	25 (21.6)	N.A. (12.98, N.A.)	104	3 (2.9)	N.A.	7.556 (2.275, 25.102) 0.0001	
NON-ASIA	42	6 (14.3)	N.A.	41	1 (2.4)	N.A. (10.15, N.A.)	5.495 (0.653, 46.273) 0.0793	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 212 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.1698
0	71	11 (15.5)	N.A.	69	3 (4.3)	N.A.	3.438 (0.957, 12.347) 0.0435	
1	87	20 (23.0)	N.A. (11.53, N.A.)	74	1 (1.4)	N.A. (10.15, N.A.)	18.193 (2.429,>99.999) <0.0001	
WEIGHT								0.7618
< 60 KG	96	20 (20.8)	N.A. (12.32, N.A.)	76	2 (2.6)	N.A.	7.838 (1.824, 33.685) 0.0011	
>= 60 KG	62	11 (17.7)	N.A.	69	2 (2.9)	N.A.	6.527 (1.446, 29.469) 0.0049	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 213 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	2 (40.0)	12.25 (11.53, N.A.)	5	0	N.E.	N.E. 0.2253	
STAGE II	5	1 (20.0)	N.A. (1.38, N.A.)	5	0	N.E.	N.E. 0.4386	
STAGE III	33	5 (15.2)	N.A. (12.32, N.A.)	46	1 (2.2)	N.A.	6.089 (0.698, 53.092) 0.0640	
STAGE IV	114	23 (20.2)	N.A.	89	3 (3.4)	N.A. (10.15, N.A.)	6.669 (1.999, 22.250) 0.0004	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 214 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8614
GX	11	2 (18.2)	N.A. (0.95, N.A.)	14	0	N.E.	N.E. 0.0766	
G1	8	2 (25.0)	12.98 (2.30, N.A.)	8	0	N.E.	N.E. 0.3173	
G2	58	15 (25.9)	N.A. (8.48, N.A.)	50	1 (2.0)	N.A. (10.15, N.A.)	14.064 (1.858,>99.999) 0.0007	
G3	28	3 (10.7)	N.A.	36	1 (2.8)	N.A.	4.050 (0.421, 38.961) 0.1912	
NOT OTHERWISE SPECIFIED	51	9 (17.6)	N.A. (11.53, N.A.)	37	2 (5.4)	N.A.	3.130 (0.674, 14.549) 0.1249	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 215 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9473
UPPER THORACIC	37	11 (29.7)	12.32 (6.64, N.A.)	25	1 (4.0)	N.A.	7.272 (0.934, 56.604) 0.0267	
MIDDLE THORACIC	50	8 (16.0)	N.A.	52	1 (1.9)	N.A. (10.15, N.A.)	9.429 (1.179, 75.423) 0.0097	
LOWER THORACIC	59	10 (16.9)	N.A.	60	2 (3.3)	N.A.	4.974 (1.079, 22.932) 0.0226	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A. (11.53, N.A.)	8	0	N.E.	N.E. 0.3938	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 216 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9996
RECURRENT - LOCO-REGIONAL	8	1 (12.5)	N.A. (11.53, N.A.)	13	0	N.E.	N.E. 0.3173	
RECURRENT - DISTANT	25	4 (16.0)	N.A. (12.32, N.A.)	27	0	N.E.	N.E. 0.1371	
DE NOVO METASTATIC	107	22 (20.6)	N.A.	81	3 (3.7)	N.A. (10.15, N.A.)	6.172 (1.843, 20.662) 0.0007	
UNRESECTABLE ADVANCED	18	4 (22.2)	N.A.	24	1 (4.2)	N.A.	5.182 (0.579, 46.379) 0.1004	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 217 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.5241
CURRENT/FORMER	136	29 (21.3)	N.A.	111	3 (2.7)	N.A.	7.982 (2.424, 26.287) <0.0001	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	1 (2.9)	N.A.	3.195 (0.287, 35.512) 0.3182	
			(12.98, N.A.)			(10.15, N.A.)		
ALCOHOL USE								0.3386
CURRENT/FORMER	126	28 (22.2)	N.A.	117	3 (2.6)	N.A.	9.181 (2.786, 30.258) <0.0001	
NEVER/UNKNOWN	32	3 (9.4)	N.A.	28	1 (3.6)	N.A.	1.321 (0.130, 13.383) 0.8134	
			(12.98, N.A.)			(10.15, N.A.)		

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 218 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.5897
<= 1	80	20 (25.0)	N.A. (12.32, N.A.)	69	2 (2.9)	N.A.	8.968 (2.092, 38.441) 0.0004	
>= 2	78	11 (14.1)	N.A.	76	2 (2.6)	N.A. (10.15, N.A.)	5.288 (1.163, 24.036) 0.0162	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9886
< 1 YEAR	128	25 (19.5)	N.A.	115	4 (3.5)	N.A.	6.080 (2.112, 17.498) 0.0001	
1 - < 3 YEARS	25	2 (8.0)	N.A. (12.32, N.A.)	21	0	N.E.	N.E. 0.3152	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 219 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9890
YES	38	6 (15.8)	N.A. (11.53, N.A.)	37	0	N.E.	N.E. 0.0356	
NO	120	25 (20.8)	N.A.	108	4 (3.7)	N.A.	6.099 (2.117, 17.574) 0.0001	
PRIOR RADIOTHERAPY								0.9906
YES	26	4 (15.4)	N.A. (11.53, N.A.)	27	0	N.E.	N.E. 0.0846	
NO	132	27 (20.5)	N.A.	118	4 (3.4)	N.A.	6.342 (2.214, 18.170) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 220 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.7371
< 10	53	10 (18.9)	N.A. (11.53, N.A.)	54	1 (1.9)	N.A.	8.911 (1.131, 70.201) 0.0124	
>= 10	92	20 (21.7)	N.A.	89	3 (3.4)	N.A.	6.988 (2.070, 23.595) 0.0003	
PD-L1 CPS II								0.2773
< 5	29	3 (10.3)	N.A.	24	1 (4.2)	N.A.	2.445 (0.254, 23.520) 0.4237	
>= 5	116	27 (23.3)	N.A. (12.98, N.A.)	119	3 (2.5)	N.A.	9.373 (2.834, 30.998) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 221 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5214
< 10%	55	10 (18.2)	N.A. (12.32, N.A.)	57	2 (3.5)	N.A. (10.15, N.A.)	4.448 (0.962, 20.560) 0.0372	
>= 10%	103	21 (20.4)	N.A.	88	2 (2.3)	N.A.	9.592 (2.242, 41.031) 0.0002	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9856
< 5%	38	7 (18.4)	N.A. (8.48, N.A.)	41	1 (2.4)	N.A.	7.240 (0.889, 58.968) 0.0304	
>= 5%	120	24 (20.0)	N.A.	104	3 (2.9)	N.A.	6.973 (2.089, 23.272) 0.0002	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 222 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	28 (17.7)	N.A.	145	5 (3.4)	N.A.	5.357 (2.064, 13.903) 0.0001	
AGE								0.9962
< 65	95	18 (18.9)	N.A.	75	3 (4.0)	N.A.	4.965 (1.460, 16.884) 0.0044	
>= 65 AND < 75	55	10 (18.2)	N.A.	58	2 (3.4)	N.A.	5.802 (1.271, 26.493) 0.0102	
>= 75	8	0	N.E.	12	0	N.E.	N.E. N.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 223 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5062
MALE	131	25 (19.1)	N.A.	122	4 (3.3)	N.A.	6.192 (2.150, 17.833) 0.0001	
FEMALE	27	3 (11.1)	N.A.	23	1 (4.3)	N.A. (10.15, N.A.)	2.660 (0.277, 25.591) 0.3781	
RACE								0.9891
ASIAN	117	23 (19.7)	N.A.	104	4 (3.8)	N.A.	5.369 (1.854, 15.549) 0.0005	
NON-ASIAN	41	5 (12.2)	N.A.	41	1 (2.4)	N.A. (10.15, N.A.)	4.620 (0.529, 40.317) 0.1297	

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Protocol: CA209648 Page 224 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9788
J/K/T	91	15 (16.5)	N.A.	85	3 (3.5)	N.A.	4.736 (1.367, 16.403) 0.0068	
REST OF ASIA	25	7 (28.0)	N.A. (3.58, N.A.)	19	1 (5.3)	N.A.	5.892 (0.724, 47.938) 0.0597	
REST OF WORLD	42	6 (14.3)	N.A.	41	1 (2.4)	N.A. (10.15, N.A.)	5.643 (0.670, 47.519) 0.0737	
REGION								0.8686
ASIA	116	22 (19.0)	N.A.	104	4 (3.8)	N.A.	5.150 (1.772, 14.971) 0.0008	
NON-ASIA	42	6 (14.3)	N.A.	41	1 (2.4)	N.A. (10.15, N.A.)	5.643 (0.670, 47.519) 0.0737	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 225 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.1777
0	71	8 (11.3)	N.A.	69	3 (4.3)	N.A.	2.421 (0.640, 9.158) 0.1781	
1	87	20 (23.0)	N.A.	74	2 (2.7)	N.A. (10.15, N.A.)	10.059 (2.345, 43.153) 0.0001	
WEIGHT								0.9069
< 60 KG	96	18 (18.8)	N.A.	76	3 (3.9)	N.A.	4.923 (1.446, 16.763) 0.0048	
>= 60 KG	62	10 (16.1)	N.A.	69	2 (2.9)	N.A.	5.901 (1.292, 26.959) 0.0093	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 226 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.7688
STAGE I	5	1 (20.0)	N.A. (2.30, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	1 (20.0)	N.A. (1.38, N.A.)	5	0	N.E.	N.E. 0.4386	
STAGE III	33	3 (9.1)	N.A. (12.39, N.A.)	46	2 (4.3)	N.A.	1.736 (0.279, 10.805) 0.5501	
STAGE IV	114	23 (20.2)	N.A.	89	3 (3.4)	N.A. (10.15, N.A.)	6.516 (1.953, 21.739) 0.0005	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 227 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.6977
GX	11	0	N.E.	14	0	N.E.	N.E. N.E.	
G1	8	1 (12.5)	N.A. (2.30, N.A.)	8	0	N.E.	N.E. 0.3173	
G2	58	15 (25.9)	N.A. (8.48, N.A.)	50	1 (2.0)	N.A. (10.15, N.A.)	14.068 (1.858,>99.999) 0.0008	
G3	28	3 (10.7)	N.A.	36	2 (5.6)	N.A.	2.098 (0.350, 12.577) 0.4102	
NOT OTHERWISE SPECIFIED	51	9 (17.6)	N.A. (12.39, N.A.)	37	2 (5.4)	N.A.	3.191 (0.687, 14.832) 0.1182	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 228 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8482
UPPER THORACIC	37	8 (21.6)	N.A. (8.48, N.A.)	25	1 (4.0)	N.A.	4.620 (0.572, 37.314) 0.1150	
MIDDLE THORACIC	50	8 (16.0)	N.A.	52	1 (1.9)	N.A. (10.15, N.A.)	9.459 (1.182, 75.665) 0.0096	
LOWER THORACIC	59	10 (16.9)	N.A.	60	3 (5.0)	N.A.	3.632 (0.999, 13.203) 0.0361	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A. (0.49, N.A.)	8	0	N.E.	N.E. 0.2166	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 229 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9913
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	0	N.E.	N.E. N.E.	
RECURRENT - DISTANT	25	4 (16.0)	N.A. (12.39, N.A.)	27	1 (3.7)	N.A.	3.488 (0.363, 33.554) 0.2488	
DE NOVO METASTATIC	107	21 (19.6)	N.A.	81	3 (3.7)	N.A. (10.15, N.A.)	5.710 (1.699, 19.187) 0.0015	
UNRESECTABLE ADVANCED	18	3 (16.7)	N.A.	24	1 (4.2)	N.A.	3.871 (0.402, 37.231) 0.2065	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 230 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.7249
CURRENT/FORMER	136	26 (19.1)	N.A.	111	4 (3.6)	N.A.	5.554 (1.934, 15.945) 0.0003	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	1 (2.9)	N.A.	3.195 (0.287, 35.512) 0.3182	
			(8.48, N.A.)			(10.15, N.A.)		
ALCOHOL USE								0.7378
CURRENT/FORMER	126	24 (19.0)	N.A.	117	4 (3.4)	N.A.	5.885 (2.039, 16.989) 0.0002	
NEVER/UNKNOWN	32	4 (12.5)	N.A.	28	1 (3.6)	N.A.	2.907 (0.316, 26.762) 0.3251	
			(8.48, N.A.)			(10.15, N.A.)		

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 231 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4062
<= 1	80	17 (21.3)	N.A.	69	2 (2.9)	N.A.	7.936 (1.831, 34.393) 0.0010	
>= 2	78	11 (14.1)	N.A.	76	3 (3.9)	N.A. (10.15, N.A.)	3.472 (0.959, 12.573) 0.0439	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3355
< 1 YEAR	128	24 (18.8)	N.A.	115	4 (3.5)	N.A.	5.718 (1.981, 16.509) 0.0003	
1 - < 3 YEARS	25	2 (8.0)	N.A. (12.39, N.A.)	21	1 (4.8)	N.A.	1.070 (0.089, 12.895) 0.9572	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 232 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9505
YES	38	6 (15.8)	N.A.	37	1 (2.7)	N.A.	5.633 (0.677, 46.891) 0.0713	
NO	120	22 (18.3)	N.A.	108	4 (3.7)	N.A.	5.244 (1.801, 15.270) 0.0007	
PRIOR RADIOTHERAPY								0.9907
YES	26	3 (11.5)	N.A. (12.39, N.A.)	27	0	N.E.	N.E. 0.1113	
NO	132	25 (18.9)	N.A.	118	5 (4.2)	N.A.	4.771 (1.824, 12.484) 0.0004	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 233 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.7415
< 10	53	7 (13.2)	N.A. (12.39, N.A.)	54	1 (1.9)	N.A.	6.183 (0.750, 50.972) 0.0543	
>= 10	92	18 (19.6)	N.A.	89	4 (4.5)	N.A.	4.882 (1.650, 14.449) 0.0015	
PD-L1 CPS II								0.4712
< 5	29	3 (10.3)	N.A.	24	1 (4.2)	N.A.	2.498 (0.260, 24.050) 0.4120	
>= 5	116	22 (19.0)	N.A.	119	4 (3.4)	N.A.	5.886 (2.023, 17.125) 0.0002	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 234 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3563
< 10%	55	6 (10.9)	N.A. (10.15, N.A.)	57	2 (3.5)	N.A.	2.132 (0.413, 11.003) 0.3560	
>= 10%	103	22 (21.4)	N.A.	88	3 (3.4)	N.A.	7.373 (2.205, 24.658) 0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7703
< 5%	38	4 (10.5)	N.A.	41	1 (2.4)	N.A.	3.718 (0.411, 33.592) 0.2104	
>= 5%	120	24 (20.0)	N.A.	104	4 (3.8)	N.A.	5.671 (1.963, 16.388) 0.0003	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 235 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
OVERALL	158	8 (5.1)	N.A.	145	23 (15.9)	N.A.	0.248 (0.108, 0.571) 0.0004	
AGE								0.7138
< 65	95	3 (3.2)	N.A.	75	5 (6.7)	N.A.	0.440 (0.104, 1.855) 0.2511	
>= 65 AND < 75	55	4 (7.3)	N.A. (19.58, N.A.)	58	14 (24.1)	N.A.	0.172 (0.049, 0.608) 0.0021	
>= 75	8	1 (12.5)	N.A. (5.06, N.A.)	12	4 (33.3)	N.A. (0.59, N.A.)	0.247 (0.027, 2.265) 0.1830	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 236 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7537
MALE	131	6 (4.6)	N.A.	122	19 (15.6)	N.A.	0.255 (0.101, 0.644) 0.0019	
FEMALE	27	2 (7.4)	N.A. (7.85, N.A.)	23	4 (17.4)	N.A.	0.179 (0.020, 1.614) 0.0847	
RACE								0.9905
ASIAN	117	8 (6.8)	N.A.	104	22 (21.2)	N.A.	0.231 (0.098, 0.544) 0.0003	
NON-ASIAN	41	0	N.E.	41	1 (2.4)	N.A.	N.E. 0.3367	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 237 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9789
J/K/T	91	7 (7.7)	N.A.	85	20 (23.5)	N.A.	0.231 (0.092, 0.578) 0.0007	
REST OF ASIA	25	1 (4.0)	N.A.	19	2 (10.5)	N.A. (6.34, N.A.)	0.302 (0.027, 3.358) 0.3017	
REST OF WORLD	42	0	N.E.	41	1 (2.4)	N.A.	N.E. 0.3300	
REGION								0.9903
ASIA	116	8 (6.9)	N.A.	104	22 (21.2)	N.A.	0.234 (0.099, 0.551) 0.0003	
NON-ASIA	42	0	N.E.	41	1 (2.4)	N.A.	N.E. 0.3300	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 238 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.3564
0	71	7 (9.9)	N.A. (19.58, N.A.)	69	16 (23.2)	N.A.	0.301 (0.121, 0.748) 0.0063	
1	87	1 (1.1)	N.A.	74	7 (9.5)	N.A.	0.122 (0.015, 0.991) 0.0187	
WEIGHT								0.9321
< 60 KG	96	6 (6.3)	N.A.	76	15 (19.7)	N.A.	0.213 (0.077, 0.591) 0.0011	
>= 60 KG	62	2 (3.2)	N.A.	69	8 (11.6)	N.A.	0.267 (0.057, 1.259) 0.0737	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 239 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8978
STAGE I	5	0	N.E.	5	3 (60.0)	2.00 (0.53, N.A.)	N.E. 0.0494	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	2 (6.1)	N.A. (12.55, N.A.)	46	10 (21.7)	N.A.	0.208 (0.045, 0.970) 0.0284	
STAGE IV	114	6 (5.3)	N.A.	89	10 (11.2)	N.A.	0.377 (0.128, 1.105) 0.0644	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 240 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9286
GX	11	0	N.E.	14	4 (28.6)	N.A. (0.76, N.A.)	N.E. 0.0721	
G1	8	0	N.E.	8	1 (12.5)	N.A. (1.64, N.A.)	N.E. 0.3173	
G2	58	1 (1.7)	N.A. (12.55, N.A.)	50	5 (10.0)	N.A.	0.161 (0.019, 1.382) 0.0569	
G3	28	0	N.E.	36	5 (13.9)	N.A.	N.E. 0.0510	
NOT OTHERWISE SPECIFIED	51	7 (13.7)	N.A. (12.55, N.A.)	37	8 (21.6)	N.A.	0.378 (0.129, 1.111) 0.0662	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 241 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.4836
UPPER THORACIC	37	3 (8.1)	N.A. (12.55, N.A.)	25	7 (28.0)	N.A. (3.12, N.A.)	0.201 (0.050, 0.801) 0.0126	
MIDDLE THORACIC	50	3 (6.0)	N.A.	52	4 (7.7)	N.A.	0.789 (0.177, 3.526) 0.7559	
LOWER THORACIC	59	2 (3.4)	N.A.	60	11 (18.3)	N.A.	0.128 (0.026, 0.629) 0.0037	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	1 (12.5)	N.A. (1.91, N.A.)	N.E. 0.2320	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 242 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.8920
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	4 (30.8)	N.A. (0.92, N.A.)	N.E. 0.0854	
RECURRENT - DISTANT	25	2 (8.0)	N.A. (12.55, N.A.)	27	7 (25.9)	N.A. (6.34, N.A.)	0.122 (0.015, 0.994) 0.0193	
DE NOVO METASTATIC	107	6 (5.6)	N.A.	81	9 (11.1)	N.A.	0.402 (0.134, 1.204) 0.0916	
UNRESECTABLE ADVANCED	18	0	N.E.	24	3 (12.5)	N.A.	N.E. 0.1200	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 243 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6059
CURRENT/FORMER	136	7 (5.1)	N.A.	111	20 (18.0)	N.A.	0.216 (0.088, 0.529) 0.0003	
NEVER/UNKNOWN	22	1 (4.5)	N.A. (7.85, N.A.)	34	3 (8.8)	N.A.	0.480 (0.049, 4.667) 0.5179	
ALCOHOL USE								0.7455
CURRENT/FORMER	126	7 (5.6)	N.A.	117	21 (17.9)	N.A.	0.237 (0.097, 0.577) 0.0006	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	2 (7.1)	N.A.	0.335 (0.029, 3.874) 0.3601	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 244 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.3325
<= 1	80	6 (7.5)	N.A.	69	12 (17.4)	N.A.	0.329 (0.120, 0.904) 0.0239	
>= 2	78	2 (2.6)	N.A.	76	11 (14.5)	N.A.	0.151 (0.033, 0.688) 0.0051	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.8535
< 1 YEAR	128	6 (4.7)	N.A.	115	16 (13.9)	N.A.	0.259 (0.095, 0.708) 0.0046	
1 - < 3 YEARS	25	2 (8.0)	N.A. (6.28, N.A.)	21	4 (19.0)	N.A. (6.34, N.A.)	0.302 (0.052, 1.747) 0.1595	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 245 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.1101
YES	38	1 (2.6)	N.A. (6.34, N.A.)	37	10 (27.0)	N.A.	0.077 (0.010, 0.602) 0.0016	
NO	120	7 (5.8)	N.A.	108	13 (12.0)	N.A.	0.371 (0.140, 0.988) 0.0391	
PRIOR RADIOTHERAPY								0.6115
YES	26	1 (3.8)	N.A. (12.55, N.A.)	27	5 (18.5)	N.A.	0.160 (0.018, 1.397) 0.0601	
NO	132	7 (5.3)	N.A.	118	18 (15.3)	N.A.	0.270 (0.107, 0.682) 0.0030	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 246 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9680
< 10	53	2 (3.8)	N.A. (12.55, N.A.)	54	7 (13.0)	N.A.	0.220 (0.044, 1.109) 0.0469	
>= 10	92	5 (5.4)	N.A.	89	16 (18.0)	N.A.	0.238 (0.084, 0.675) 0.0036	
PD-L1 CPS II								0.9899
< 5	29	0	N.E.	24	5 (20.8)	N.A.	N.E. 0.0133	
>= 5	116	7 (6.0)	N.A.	119	18 (15.1)	N.A.	0.306 (0.124, 0.758) 0.0070	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 247 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3962
< 10%	55	3 (5.5)	N.A.	57	6 (10.5)	N.A.	0.386 (0.095, 1.569) 0.1687	
>= 10%	103	5 (4.9)	N.A.	88	17 (19.3)	N.A.	0.187 (0.063, 0.557) 0.0007	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7451
< 5%	38	1 (2.6)	N.A.	41	5 (12.2)	N.A.	0.178 (0.021, 1.537) 0.0778	
>= 5%	120	7 (5.8)	N.A.	104	18 (17.3)	N.A.	0.250 (0.098, 0.634) 0.0017	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 248 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	6 (3.8)	N.A.	145	21 (14.5)	N.A.	0.236 (0.095, 0.590) 0.0008	
AGE								0.4914
< 65	95	3 (3.2)	N.A.	75	5 (6.7)	N.A.	0.419 (0.099, 1.778) 0.2242	
>= 65 AND < 75	55	2 (3.6)	N.A.	58	13 (22.4)	N.A.	0.150 (0.034, 0.667) 0.0040	
>= 75	8	1 (12.5)	N.A. (3.25, N.A.)	12	3 (25.0)	N.A. (0.82, N.A.)	0.424 (0.044, 4.087) 0.4441	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 249 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9907
MALE	131	6 (4.6)	N.A. (10.61, N.A.)	122	18 (14.8)	N.A. (10.61, N.A.)	0.280 (0.110, 0.715) 0.0046	
FEMALE	27	0	N.E.	23	3 (13.0)	N.A. (5.55, N.A.)	N.E. 0.0481	
RACE								0.1484
ASIAN	117	3 (2.6)	N.A.	104	16 (15.4)	N.A.	0.153 (0.044, 0.526) 0.0006	
NON-ASIAN	41	3 (7.3)	N.A. (10.61, N.A.)	41	5 (12.2)	N.A. (10.61, N.A.)	0.522 (0.120, 2.276) 0.3795	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 250 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4967
J/K/T	91	3 (3.3)	N.A.	85	14 (16.5)	N.A.	0.188 (0.054, 0.658) 0.0035	
REST OF ASIA	25	0	N.E.	19	2 (10.5)	N.A. (5.55, N.A.)	N.E. 0.0595	
REST OF WORLD	42	3 (7.1)	N.A.	41	5 (12.2)	N.A. (10.61, N.A.)	0.501 (0.115, 2.192) 0.3506	
REGION								0.1643
ASIA	116	3 (2.6)	N.A.	104	16 (15.4)	N.A.	0.155 (0.045, 0.532) 0.0007	
NON-ASIA	42	3 (7.1)	N.A.	41	5 (12.2)	N.A. (10.61, N.A.)	0.501 (0.115, 2.192) 0.3506	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 251 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6578
0	71	4 (5.6)	N.A.	69	12 (17.4)	N.A. (10.61, N.A.)	0.268 (0.085, 0.840) 0.0157	
1	87	2 (2.3)	N.A.	74	9 (12.2)	N.A.	0.191 (0.041, 0.887) 0.0182	
WEIGHT								0.8089
< 60 KG	96	3 (3.1)	N.A.	76	8 (10.5)	N.A.	0.276 (0.073, 1.051) 0.0442	
>= 60 KG	62	3 (4.8)	N.A.	69	13 (18.8)	N.A. (10.61, N.A.)	0.216 (0.060, 0.781) 0.0109	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 252 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	0	N.E.	5	1 (20.0)	N.A. (3.65, N.A.)	N.E. 0.2636	
STAGE II	5	0	N.E.	5	2 (40.0)	5.55 (1.84, N.A.)	N.E. 0.0343	
STAGE III	33	0	N.E.	46	7 (15.2)	10.61 (8.25, N.A.)	N.E. 0.0053	
STAGE IV	114	6 (5.3)	N.A.	89	11 (12.4)	N.A.	0.442 (0.163, 1.195) 0.0981	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 253 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	1 (9.1)	N.M.E.	14	3 (21.4)	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	3 (37.5)	N.M.E.	N.M.E.	
G2	58	3 (5.2)	N.M.E.	50	3 (6.0)	N.M.E.	N.M.E.	
G3	28	1 (3.6)	N.M.E.	36	6 (16.7)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	1 (2.0)	N.M.E.	37	6 (16.2)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 254 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9332
UPPER THORACIC	37	1 (2.7)	N.A.	25	4 (16.0)	N.A.	0.159 (0.018, 1.427) 0.0599	
MIDDLE THORACIC	50	2 (4.0)	N.A.	52	6 (11.5)	N.A. (8.25, N.A.)	0.351 (0.071, 1.746) 0.1812	
LOWER THORACIC	59	3 (5.1)	N.A.	60	11 (18.3)	N.A. (10.61, N.A.)	0.231 (0.062, 0.862) 0.0184	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 255 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (1) (mon)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (1) (mon)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	3 (23.1)	10.61 (5.49, N.A.)	N.E. 0.0887	
RECURRENT - DISTANT	25	0	N.E.	27	6 (22.2)	N.A. (5.55, N.A.)	N.E. 0.0128	
DE NOVO METASTATIC	107	6 (5.6)	N.A.	81	11 (13.6)	N.A.	0.428 (0.158, 1.158) 0.0853	
UNRESECTABLE ADVANCED	18	0	N.E.	24	1 (4.2)	N.A. (8.25, N.A.)	N.E. 0.2801	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 256 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9883
CURRENT/FORMER	136	6 (4.4)	N.A.	111	18 (16.2)	N.A. (10.61, N.A.)	0.241 (0.094, 0.614) 0.0013	
NEVER/UNKNOWN	22	0	N.E.	34	3 (8.8)	N.A.	N.E. 0.1396	
ALCOHOL USE								0.9899
CURRENT/FORMER	126	6 (4.8)	N.A.	117	16 (13.7)	N.A. (10.61, N.A.)	0.318 (0.123, 0.819) 0.0125	
NEVER/UNKNOWN	32	0	N.E.	28	5 (17.9)	N.A. (5.55, N.A.)	N.E. 0.0091	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 257 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.8965
<= 1	80	4 (5.0)	N.A. (10.61, N.A.)	69	14 (20.3)	N.A. (10.61, N.A.)	0.219 (0.071, 0.669) 0.0036	
>= 2	78	2 (2.6)	N.A.	76	7 (9.2)	N.A.	0.282 (0.059, 1.358) 0.0915	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9914
< 1 YEAR	128	6 (4.7)	N.A.	115	16 (13.9)	N.A.	0.323 (0.126, 0.827) 0.0132	
1 - < 3 YEARS	25	0	N.E.	21	3 (14.3)	10.61 (10.61, N.A.)	N.E. 0.0306	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 258 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4076
YES	38	1 (2.6)	N.A.	37	7 (18.9)	N.A. (10.61, N.A.)	0.102 (0.012, 0.856) 0.0112	
NO	120	5 (4.2)	N.A.	108	14 (13.0)	N.A.	0.316 (0.113, 0.880) 0.0200	
PRIOR RADIOTHERAPY								0.9872
YES	26	0	N.E.	27	6 (22.2)	10.61 (5.55, N.A.)	N.E. 0.0060	
NO	132	6 (4.5)	N.A.	118	15 (12.7)	N.A.	0.349 (0.135, 0.903) 0.0231	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 259 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9473
< 10	53	2 (3.8)	N.A.	54	7 (13.0)	N.A.	0.295 (0.061, 1.420) 0.1051	
>= 10	92	4 (4.3)	N.A.	89	13 (14.6)	N.A. (10.61, N.A.)	0.260 (0.084, 0.806) 0.0124	
PD-L1 CPS II								0.9907
< 5	29	0	N.E.	24	4 (16.7)	N.A.	N.E. 0.0309	
>= 5	116	6 (5.2)	N.A.	119	16 (13.4)	N.A.	0.346 (0.134, 0.892) 0.0217	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 260 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Blood Creatinine Increased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.4754
< 10%	55	4 (7.3)	N.A. (10.61, N.A.)	57	11 (19.3)	N.A.	0.311 (0.097, 1.000) 0.0389	
>= 10%	103	2 (1.9)	N.A.	88	10 (11.4)	N.A.	0.168 (0.037, 0.769) 0.0090	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7907
< 5%	38	3 (7.9)	N.A. (6.41, N.A.)	41	10 (24.4)	10.61	0.268 (0.072, 0.999) 0.0363	
>= 5%	120	3 (2.5)	N.A.	104	11 (10.6)	N.A.	0.232 (0.065, 0.835) 0.0149	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 261 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	5 (3.2)	N.A.	145	20 (13.8)	N.A.	0.216 (0.081, 0.576) 0.0008	
AGE								0.8404
< 65	95	3 (3.2)	N.A.	75	6 (8.0)	N.A.	0.395 (0.099, 1.583) 0.1742	
>= 65 AND < 75	55	2 (3.6)	N.A.	58	9 (15.5)	N.A. (7.82, N.A.)	0.198 (0.042, 0.929) 0.0232	
>= 75	8	0	N.E.	12	5 (41.7)	N.A. (0.53, N.A.)	N.E. 0.0357	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 262 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8389
MALE	131	4 (3.1)	N.A.	122	17 (13.9)	N.A.	0.203 (0.068, 0.605) 0.0015	
FEMALE	27	1 (3.7)	N.A.	23	3 (13.0)	N.A.	0.279 (0.029, 2.685) 0.2375	
RACE								0.9910
ASIAN	117	5 (4.3)	N.A.	104	18 (17.3)	N.A.	0.225 (0.083, 0.608) 0.0013	
NON-ASIAN	41	0	N.E.	41	2 (4.9)	N.A.	N.E. 0.1714	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 263 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9565
J/K/T	91	4 (4.4)	N.A.	85	16 (18.8)	N.A.	0.223 (0.074, 0.669) 0.0034	
REST OF ASIA	25	1 (4.0)	N.A. (6.77, N.A.)	19	2 (10.5)	N.A. (4.67, N.A.)	0.221 (0.019, 2.506) 0.1839	
REST OF WORLD	42	0	N.E.	41	2 (4.9)	N.A.	N.E. 0.1656	
REGION								0.9909
ASIA	116	5 (4.3)	N.A.	104	18 (17.3)	N.A.	0.228 (0.085, 0.616) 0.0014	
NON-ASIA	42	0	N.E.	41	2 (4.9)	N.A.	N.E. 0.1656	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 264 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.7276
0	71	4 (5.6)	N.A.	69	17 (24.6)	N.A.	0.197 (0.066, 0.586) 0.0012	
1	87	1 (1.1)	N.A.	74	3 (4.1)	N.A.	0.260 (0.027, 2.505) 0.2093	
WEIGHT								0.5841
< 60 KG	96	3 (3.1)	N.A.	76	13 (17.1)	N.A.	0.175 (0.050, 0.615) 0.0021	
>= 60 KG	62	2 (3.2)	N.A.	69	7 (10.1)	N.A.	0.291 (0.060, 1.407) 0.1028	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 265 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9970
STAGE I	5	1 (20.0)	N.A. (0.46, N.A.)	5	2 (40.0)	N.A. (3.15, N.A.)	0.486 (0.044, 5.422) 0.5492	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	0	N.E.	46	8 (17.4)	N.A.	N.E. 0.0118	
STAGE IV	114	4 (3.5)	N.A.	89	10 (11.2)	N.A.	0.304 (0.095, 0.973) 0.0337	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	2 (14.3)	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
G2	58	2 (3.4)	N.M.E.	50	5 (10.0)	N.M.E.	N.M.E.	
G3	28	0	N.M.E.	36	6 (16.7)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	3 (5.9)	N.M.E.	37	6 (16.2)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 267 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7688
UPPER THORACIC	37	2 (5.4)	N.A. (4.67, N.A.)	25	5 (20.0)	N.A. (1.91, N.A.)	0.258 (0.050, 1.332) 0.0813	
MIDDLE THORACIC	50	2 (4.0)	N.A.	52	5 (9.6)	N.A.	0.432 (0.084, 2.227) 0.3016	
LOWER THORACIC	59	1 (1.7)	N.A.	60	9 (15.0)	N.A.	0.098 (0.012, 0.776) 0.0066	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	1 (12.5)	N.A.	N.E. 0.2320	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 268 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9780
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	4 (30.8)	N.A. (1.84, N.A.)	N.E. 0.0801	
RECURRENT - DISTANT	25	0	N.E.	27	5 (18.5)	N.A. (6.34, N.A.)	N.E. 0.0224	
DE NOVO METASTATIC	107	4 (3.7)	N.A.	81	9 (11.1)	N.A.	0.321 (0.098, 1.047) 0.0473	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A.	24	2 (8.3)	N.A.	0.662 (0.060, 7.300) 0.7343	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 269 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9889
CURRENT/FORMER	136	5 (3.7)	N.A.	111	17 (15.3)	N.A.	0.219 (0.081, 0.596) 0.0011	
NEVER/UNKNOWN	22	0	N.E.	34	3 (8.8)	N.A.	N.E. 0.1750	
ALCOHOL USE								0.9909
CURRENT/FORMER	126	5 (4.0)	N.A.	117	17 (14.5)	N.A.	0.256 (0.094, 0.694) 0.0039	
NEVER/UNKNOWN	32	0	N.E.	28	3 (10.7)	N.A.	N.E. 0.0725	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 270 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.6548
<= 1	80	3 (3.8)	N.A.	69	9 (13.0)	N.A.	0.269 (0.073, 0.993) 0.0346	
>= 2	78	2 (2.6)	N.A.	76	11 (14.5)	N.A.	0.174 (0.038, 0.785) 0.0100	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9923
< 1 YEAR	128	4 (3.1)	N.A.	115	15 (13.0)	N.A.	0.224 (0.074, 0.677) 0.0037	
1 - < 3 YEARS	25	0	N.E.	21	3 (14.3)	N.A. (6.34, N.A.)	N.E. 0.0530	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 271 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9912
YES	38	0	N.E.	37	9 (24.3)	N.A. (6.34, N.A.)	N.E. 0.0009	
NO	120	5 (4.2)	N.A.	108	11 (10.2)	N.A.	0.406 (0.141, 1.172) 0.0850	
PRIOR RADIOTHERAPY								0.8452
YES	26	1 (3.8)	N.A.	27	5 (18.5)	N.A.	0.198 (0.023, 1.699) 0.1005	
NO	132	4 (3.0)	N.A.	118	15 (12.7)	N.A.	0.225 (0.074, 0.678) 0.0038	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 272 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.4937
< 10	53	2 (3.8)	N.A.	54	5 (9.3)	N.A.	0.408 (0.079, 2.105) 0.2694	
>= 10	92	3 (3.3)	N.A.	89	15 (16.9)	N.A.	0.180 (0.052, 0.624) 0.0024	
PD-L1 CPS II								0.9912
< 5	29	0	N.E.	24	4 (16.7)	N.A.	N.E. 0.0288	
>= 5	116	5 (4.3)	N.A.	119	16 (13.4)	N.A.	0.302 (0.110, 0.826) 0.0135	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 273 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: White Blood Cell Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.6199
< 10%	55	2 (3.6)	N.A.	57	6 (10.5)	N.A.	0.302 (0.061, 1.503) 0.1211	
>= 10%	103	3 (2.9)	N.A.	88	14 (15.9)	N.A.	0.181 (0.052, 0.629) 0.0025	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.6803
< 5%	38	1 (2.6)	N.A.	41	3 (7.3)	N.A.	0.342 (0.036, 3.288) 0.3299	
>= 5%	120	4 (3.3)	N.A.	104	17 (16.3)	N.A.	0.193 (0.065, 0.574) 0.0010	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 274 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	4 (2.5)	N.A.	145	13 (9.0)	N.A.	0.248 (0.080, 0.771) 0.0094	
AGE								N.M.E.
< 65	95	0	N.M.E.	75	7 (9.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	3 (5.5)	N.M.E.	58	4 (6.9)	N.M.E.	N.M.E.	
>= 75	8	1 (12.5)	N.M.E.	12	2 (16.7)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 275 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9883
MALE	131	2 (1.5)	N.A.	122	13 (10.7)	N.A.	0.120 (0.026, 0.544) 0.0012	
FEMALE	27	2 (7.4)	N.A.	23	0	N.E.	N.E. 0.1970	
RACE								0.9910
ASIAN	117	4 (3.4)	N.A.	104	9 (8.7)	N.A.	0.338 (0.102, 1.114) 0.0621	
NON-ASIAN	41	0	N.E.	41	4 (9.8)	N.A.	N.E. 0.0502	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 276 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	4 (4.4)	N.M.E.	85	5 (5.9)	N.M.E.	N.M.E.	
REST OF ASIA	25	0	N.M.E.	19	4 (21.1)	N.M.E.	N.M.E.	
REST OF WORLD	42	0	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	
REGION								0.9908
ASIA	116	4 (3.4)	N.A.	104	9 (8.7)	N.A.	0.343 (0.104, 1.128) 0.0655	
NON-ASIA	42	0	N.E.	41	4 (9.8)	N.A.	N.E. 0.0471	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 277 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.5986
0	71	3 (4.2)	N.A.	69	8 (11.6)	N.A.	0.332 (0.088, 1.252) 0.0870	
1	87	1 (1.1)	N.A.	74	5 (6.8)	N.A.	0.110 (0.011, 1.068) 0.0284	
WEIGHT								0.6133
< 60 KG	96	2 (2.1)	N.A.	76	4 (5.3)	N.A.	0.328 (0.059, 1.833) 0.1828	
>= 60 KG	62	2 (3.2)	N.A.	69	9 (13.0)	N.A.	0.236 (0.051, 1.095) 0.0447	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 278 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	0	N.E.	46	4 (8.7)	N.A.	N.E. 0.0869	
STAGE IV	114	4 (3.5)	N.A.	89	9 (10.1)	N.A.	0.305 (0.092, 1.007) 0.0396	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 279 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	1 (7.1)	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
G2	58	2 (3.4)	N.M.E.	50	2 (4.0)	N.M.E.	N.M.E.	
G3	28	0	N.M.E.	36	7 (19.4)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	2 (3.9)	N.M.E.	37	2 (5.4)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 280 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.5261
UPPER THORACIC	37	2 (5.4)	N.A.	25	0	N.E.	N.E. 0.2620	
MIDDLE THORACIC	50	1 (2.0)	N.A.	52	1 (1.9)	N.A.	1.076 (0.067, 17.200) 0.9588	
LOWER THORACIC	59	1 (1.7)	N.A.	60	10 (16.7)	N.A.	0.053 (0.006, 0.508) 0.0014	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	2 (25.0)	N.A. (0.95, N.A.)	N.E. 0.0720	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 281 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	1 (7.7)	N.A.	N.E. 0.4250	
RECURRENT - DISTANT	25	0	N.E.	27	2 (7.4)	N.A.	N.E. 0.1697	
DE NOVO METASTATIC	107	4 (3.7)	N.A.	81	9 (11.1)	N.A.	0.285 (0.086, 0.949) 0.0300	
UNRESECTABLE ADVANCED	18	0	N.E.	24	1 (4.2)	N.A.	N.E. 0.3865	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 282 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.7646
CURRENT/FORMER	136	3 (2.2)	N.A.	111	9 (8.1)	N.A.	0.224 (0.058, 0.860) 0.0181	
NEVER/UNKNOWN	22	1 (4.5)	N.A.	34	4 (11.8)	N.A.	0.349 (0.039, 3.144) 0.3261	
ALCOHOL USE								0.6508
CURRENT/FORMER	126	3 (2.4)	N.A.	117	11 (9.4)	N.A.	0.213 (0.058, 0.786) 0.0112	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	2 (7.1)	N.A.	0.411 (0.037, 4.559) 0.4543	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 283 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.2506
<= 1	80	2 (2.5)	N.A.	69	10 (14.5)	N.A.	0.162 (0.035, 0.738) 0.0072	
>= 2	78	2 (2.6)	N.A.	76	3 (3.9)	N.A.	0.449 (0.068, 2.982) 0.3975	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9934
< 1 YEAR	128	4 (3.1)	N.A.	115	12 (10.4)	N.A.	0.258 (0.082, 0.812) 0.0130	
1 - < 3 YEARS	25	0	N.E.	21	1 (4.8)	N.A.	N.E. 0.2604	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 284 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9911
YES	38	0	N.E.	37	3 (8.1)	N.A.	N.E. 0.0697	
NO	120	4 (3.3)	N.A.	108	10 (9.3)	N.A.	0.320 (0.099, 1.037) 0.0459	
PRIOR RADIOTHERAPY								0.9929
YES	26	0	N.E.	27	3 (11.1)	N.A.	N.E. 0.0824	
NO	132	4 (3.0)	N.A.	118	10 (8.5)	N.A.	0.311 (0.096, 1.008) 0.0402	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 285 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	1 (1.9)	N.M.E.	54	6 (11.1)	N.M.E.	N.M.E.	
>= 10	92	2 (2.2)	N.M.E.	89	7 (7.9)	N.M.E.	N.M.E.	
PD-L1 CPS II								0.9930
< 5	29	0	N.E.	24	2 (8.3)	N.A. (5.82, N.A.)	N.E. 0.1230	
>= 5	116	3 (2.6)	N.A.	119	11 (9.2)	N.A.	0.245 (0.067, 0.893) 0.0215	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 286 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Platelet Count Decreased

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	2 (3.6)	N.M.E.	57	6 (10.5)	N.M.E.	N.M.E.	
>= 10%	103	2 (1.9)	N.M.E.	88	7 (8.0)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7376
< 5%	38	1 (2.6)	N.A.	41	5 (12.2)	N.A.	0.182 (0.021, 1.558) 0.0802	
>= 5%	120	3 (2.5)	N.A.	104	8 (7.7)	N.A.	0.281 (0.073, 1.088) 0.0509	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 287 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	12 (7.6)	N.A.	145	3 (2.1)	N.A.	3.335 (0.922, 12.067) 0.0518	
AGE								N.M.E.
< 65	95	6 (6.3)	N.M.E.	75	0	N.M.E.	N.M.E.	
>= 65 AND < 75	55	3 (5.5)	N.M.E.	58	3 (5.2)	N.M.E.	N.M.E.	
>= 75	8	3 (37.5)	N.M.E.	12	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 288 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9939
MALE	131	10 (7.6)	N.A.	122	3 (2.5)	N.A.	2.762 (0.739, 10.330) 0.1159	
FEMALE	27	2 (7.4)	N.A.	23	0	N.E.	N.E. 0.1838	
RACE								0.9997
ASIAN	117	12 (10.3)	N.A.	104	3 (2.9)	N.A.	3.219 (0.887, 11.685) 0.0604	
NON-ASIAN	41	0	N.E.	41	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 289 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								>0.9999
J/K/T	91	10 (11.0)	N.A.	85	3 (3.5)	N.A.	2.882 (0.767, 10.837) 0.1013	
REST OF ASIA	25	2 (8.0)	N.A.	19	0	N.E.	N.E. 0.2505	
REST OF WORLD	42	0	N.E.	41	0	N.E.	N.E. N.E.	
REGION								0.9997
ASIA	116	12 (10.3)	N.A.	104	3 (2.9)	N.A.	3.262 (0.899, 11.839) 0.0572	
NON-ASIA	42	0	N.E.	41	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 290 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	8 (11.3)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
1	87	4 (4.6)	N.M.E.	74	2 (2.7)	N.M.E.	N.M.E.	
WEIGHT								0.6369
< 60 KG	96	10 (10.4)	N.A. (19.12, N.A.)	76	2 (2.6)	N.A.	3.530 (0.749, 16.642) 0.0888	
>= 60 KG	62	2 (3.2)	N.A.	69	1 (1.4)	N.A.	2.259 (0.205, 24.926) 0.4940	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 291 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	2 (40.0)	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE II	5	1 (20.0)	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE III	33	2 (6.1)	N.M.E.	46	1 (2.2)	N.M.E.	N.M.E.	
STAGE IV	114	7 (6.1)	N.M.E.	89	2 (2.2)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 292 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	3 (37.5)	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
G2	58	4 (6.9)	N.M.E.	50	0	N.M.E.	N.M.E.	
G3	28	2 (7.1)	N.M.E.	36	1 (2.8)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	3 (5.9)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 293 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								>0.9999
UPPER THORACIC	37	2 (5.4)	N.A.	25	0	N.E.	N.E. 0.2365	
MIDDLE THORACIC	50	2 (4.0)	N.A.	52	0	N.E.	N.E. 0.1314	
LOWER THORACIC	59	7 (11.9)	N.A.	60	3 (5.0)	N.A.	2.226 (0.560, 8.841) 0.2435	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (19.12, N.A.)	8	0	N.E.	N.E. N.A.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 294 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	1 (12.5)	N.M.E.	13	0	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	3 (12.0)	N.M.E.	27	1 (3.7)	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	7 (6.5)	N.M.E.	81	2 (2.5)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.M.E.	24	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 295 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9926
CURRENT/FORMER	136	12 (8.8)	N.A.	111	2 (1.8)	N.A.	4.459 (0.980, 20.286) 0.0345	
NEVER/UNKNOWN	22	0	N.E.	34	1 (2.9)	N.A.	N.E. 0.4028	
ALCOHOL USE								0.9939
CURRENT/FORMER	126	11 (8.7)	N.A.	117	3 (2.6)	N.A.	3.022 (0.824, 11.082) 0.0801	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	0	N.E.	N.E. 0.2963	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	7 (8.8)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
>= 2	78	5 (6.4)	N.M.E.	76	2 (2.6)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3741
< 1 YEAR	128	8 (6.3)	N.A.	115	2 (1.7)	N.A.	3.301 (0.687, 15.867) 0.1144	
1 - < 3 YEARS	25	1 (4.0)	N.A.	21	1 (4.8)	N.A.	0.832 (0.052, 13.318) 0.8966	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 297 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								N.M.E.
YES	38	5 (13.2)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	
NO	120	7 (5.8)	N.M.E.	108	2 (1.9)	N.M.E.	N.M.E.	
PRIOR RADIOTHERAPY								0.9934
YES	26	2 (7.7)	N.A. (19.12, N.A.)	27	0	N.E.	N.E. 0.2600	
NO	132	10 (7.6)	N.A.	118	3 (2.5)	N.A.	2.903 (0.787, 10.709) 0.0938	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 298 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	6 (11.3)	N.M.E.	54	1 (1.9)	N.M.E.	N.M.E.	
>= 10	92	4 (4.3)	N.M.E.	89	2 (2.2)	N.M.E.	N.M.E.	
PD-L1 CPS II								0.2631
< 5	29	1 (3.4)	N.A. (6.54, N.A.)	24	1 (4.2)	N.A.	0.645 (0.038, 10.832) 0.7593	
>= 5	116	9 (7.8)	N.A.	119	2 (1.7)	N.A.	4.486 (0.955, 21.079) 0.0375	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 299 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	4 (7.3)	N.M.E.	57	2 (3.5)	N.M.E.	N.M.E.	
>= 10%	103	8 (7.8)	N.M.E.	88	1 (1.1)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								N.M.E.
< 5%	38	4 (10.5)	N.M.E.	41	2 (4.9)	N.M.E.	N.M.E.	
>= 5%	120	8 (6.7)	N.M.E.	104	1 (1.0)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 300 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	8 (5.1)	N.A.	145	30 (20.7)	N.A.	0.220 (0.101, 0.480) <0.0001	
AGE								0.7609
< 65	95	5 (5.3)	N.A.	75	15 (20.0)	N.A.	0.241 (0.088, 0.664) 0.0029	
>= 65 AND < 75	55	2 (3.6)	N.A.	58	12 (20.7)	N.A.	0.159 (0.036, 0.710) 0.0060	
>= 75	8	1 (12.5)	N.A. (3.09, N.A.)	12	3 (25.0)	N.A. (1.05, N.A.)	0.428 (0.044, 4.127) 0.4500	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 301 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9993
MALE	131	8 (6.1)	N.A.	122	30 (24.6)	N.A.	0.218 (0.100, 0.475) <0.0001	
FEMALE	27	0	N.E.	23	0	N.E.	N.E. N.E.	
RACE								0.9890
ASIAN	117	8 (6.8)	N.A.	104	27 (26.0)	N.A.	0.226 (0.103, 0.498) <0.0001	
NON-ASIAN	41	0	N.E.	41	3 (7.3)	N.A.	N.E. 0.0870	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 302 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.7267
J/K/T	91	7 (7.7)	N.A.	85	26 (30.6)	N.A.	0.215 (0.093, 0.495) <0.0001	
REST OF ASIA	25	1 (4.0)	N.A. (6.90, N.A.)	19	1 (5.3)	N.A.	0.650 (0.040, 10.477) 0.7594	
REST OF WORLD	42	0	N.E.	41	3 (7.3)	N.A.	N.E. 0.0827	
REGION								0.9889
ASIA	116	8 (6.9)	N.A.	104	27 (26.0)	N.A.	0.228 (0.104, 0.503) <0.0001	
NON-ASIA	42	0	N.E.	41	3 (7.3)	N.A.	N.E. 0.0827	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 303 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.8183
0	71	5 (7.0)	N.A.	69	20 (29.0)	N.A.	0.203 (0.076, 0.542) 0.0004	
1	87	3 (3.4)	N.A.	74	10 (13.5)	N.A.	0.245 (0.067, 0.891) 0.0211	
WEIGHT								0.8903
< 60 KG	96	5 (5.2)	N.A.	76	17 (22.4)	N.A.	0.205 (0.076, 0.556) 0.0006	
>= 60 KG	62	3 (4.8)	N.A.	69	13 (18.8)	N.A.	0.235 (0.067, 0.824) 0.0144	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 304 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9961
STAGE I	5	1 (20.0)	N.A. (6.11, N.A.)	5	2 (40.0)	N.A. (0.07, N.A.)	0.356 (0.032, 4.011) 0.3834	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	0	N.E.	46	11 (23.9)	N.A.	N.E. 0.0029	
STAGE IV	114	7 (6.1)	N.A.	89	17 (19.1)	N.A.	0.293 (0.121, 0.706) 0.0040	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 305 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9720
GX	11	2 (18.2)	N.A. (0.62, N.A.)	14	6 (42.9)	N.A. (0.10, N.A.)	0.353 (0.071, 1.752) 0.1848	
G1	8	0	N.E.	8	6 (75.0)	1.13 (0.03, N.A.)	N.E. 0.0029	
G2	58	2 (3.4)	N.A.	50	8 (16.0)	N.A.	0.197 (0.042, 0.926) 0.0231	
G3	28	0	N.E.	36	3 (8.3)	N.A.	N.E. 0.1219	
NOT OTHERWISE SPECIFIED	51	4 (7.8)	N.A.	37	7 (18.9)	N.A.	0.367 (0.107, 1.260) 0.0988	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 306 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.5860
UPPER THORACIC	37	1 (2.7)	N.A. (1.25, N.A.)	25	7 (28.0)	N.A. (0.07, N.A.)	0.084 (0.010, 0.683) 0.0032	
MIDDLE THORACIC	50	5 (10.0)	N.A.	52	12 (23.1)	N.A.	0.396 (0.140, 1.125) 0.0737	
LOWER THORACIC	59	2 (3.4)	N.A.	60	10 (16.7)	N.A.	0.189 (0.041, 0.861) 0.0164	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	1 (12.5)	N.A.	N.E. 0.2410	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 307 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.8758
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	2 (15.4)	N.A. (1.08, N.A.)	N.E. 0.2468	
RECURRENT - DISTANT	25	1 (4.0)	N.A.	27	7 (25.9)	N.A. (5.16, N.A.)	0.132 (0.016, 1.074) 0.0258	
DE NOVO METASTATIC	107	7 (6.5)	N.A.	81	14 (17.3)	N.A.	0.348 (0.140, 0.863) 0.0186	
UNRESECTABLE ADVANCED	18	0	N.E.	24	7 (29.2)	N.A. (2.86, N.A.)	N.E. 0.0124	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 308 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9871
CURRENT/FORMER	136	8 (5.9)	N.A.	111	27 (24.3)	N.A.	0.212 (0.096, 0.467) <0.0001	
NEVER/UNKNOWN	22	0	N.E.	34	3 (8.8)	N.A.	N.E. 0.1567	
ALCOHOL USE								0.9333
CURRENT/FORMER	126	7 (5.6)	N.A.	117	26 (22.2)	N.A.	0.223 (0.097, 0.513) 0.0001	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	4 (14.3)	N.A.	0.207 (0.023, 1.850) 0.1212	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 309 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4793
<= 1	80	3 (3.8)	N.A.	69	15 (21.7)	N.A.	0.159 (0.046, 0.550) 0.0009	
>= 2	78	5 (6.4)	N.A.	76	15 (19.7)	N.A.	0.285 (0.103, 0.784) 0.0103	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9898
< 1 YEAR	128	8 (6.3)	N.A.	115	24 (20.9)	N.A.	0.268 (0.121, 0.598) 0.0006	
1 - < 3 YEARS	25	0	N.E.	21	4 (19.0)	N.A. (5.16, N.A.)	N.E. 0.0183	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
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(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 310 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.3370
YES	38	1 (2.6)	N.A.	37	9 (24.3)	N.A.	0.088 (0.011, 0.698) 0.0038	
NO	120	7 (5.8)	N.A.	108	21 (19.4)	N.A.	0.274 (0.116, 0.644) 0.0016	
PRIOR RADIOTHERAPY								0.9904
YES	26	0	N.E.	27	3 (11.1)	N.A.	N.E. 0.0852	
NO	132	8 (6.1)	N.A.	118	27 (22.9)	N.A.	0.235 (0.107, 0.518) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 311 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.6256
< 10	53	3 (5.7)	N.A.	54	12 (22.2)	N.A.	0.228 (0.064, 0.808) 0.0128	
>= 10	92	3 (3.3)	N.A.	89	18 (20.2)	N.A.	0.147 (0.043, 0.500) 0.0004	
PD-L1 CPS II								0.4441
< 5	29	2 (6.9)	N.A.	24	5 (20.8)	N.A.	0.314 (0.061, 1.620) 0.1450	
>= 5	116	4 (3.4)	N.A.	119	25 (21.0)	N.A.	0.147 (0.051, 0.423) <0.0001	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 312 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.6803
< 10%	55	3 (5.5)	N.A.	57	10 (17.5)	N.A.	0.281 (0.077, 1.023) 0.0408	
>= 10%	103	5 (4.9)	N.A.	88	20 (22.7)	N.A.	0.193 (0.072, 0.515) 0.0003	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9260
< 5%	38	2 (5.3)	N.A.	41	9 (22.0)	N.A.	0.210 (0.045, 0.974) 0.0286	
>= 5%	120	6 (5.0)	N.A.	104	21 (20.2)	N.A.	0.224 (0.091, 0.556) 0.0004	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 313 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	44 (27.8)	N.A. (18.60, N.A.)	145	54 (37.2)	N.A. (6.87, N.A.)	0.652 (0.434, 0.978) 0.0374	
AGE								0.3337
< 65	95	29 (30.5)	N.A. (12.98, N.A.)	75	31 (41.3)	8.61 (5.42, N.A.)	0.728 (0.438, 1.210) 0.2185	
>= 65 AND < 75	55	10 (18.2)	N.A. (18.60, N.A.)	58	19 (32.8)	N.A. (5.55, N.A.)	0.434 (0.196, 0.961) 0.0346	
>= 75	8	5 (62.5)	8.38 (0.92, N.A.)	12	4 (33.3)	N.A. (1.25, N.A.)	1.077 (0.258, 4.496) 0.9188	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 314 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1226
MALE	131	35 (26.7)	N.A. (21.55, N.A.)	122	49 (40.2)	8.61 (5.49, N.A.)	0.577 (0.371, 0.898) 0.0135	
FEMALE	27	9 (33.3)	18.60 (5.52, N.A.)	23	5 (21.7)	N.A. (5.55, N.A.)	1.355 (0.443, 4.150) 0.5928	
RACE								0.1899
ASIAN	117	26 (22.2)	N.A. (18.60, N.A.)	104	36 (34.6)	N.A. (7.43, N.A.)	0.512 (0.304, 0.863) 0.0106	
NON-ASIAN	41	18 (43.9)	N.A. (2.07, N.A.)	41	18 (43.9)	6.87 (3.68, N.A.)	1.040 (0.540, 2.003) 0.9051	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 315 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.3993
J/K/T	91	16 (17.6)	N.A. (21.55, N.A.)	85	26 (30.6)	N.A. (7.43, N.A.)	0.449 (0.234, 0.865) 0.0140	
REST OF ASIA	25	10 (40.0)	12.98 (2.33, N.A.)	19	10 (52.6)	2.56 (1.71, N.A.)	0.570 (0.229, 1.416) 0.2259	
REST OF WORLD	42	18 (42.9)	N.A. (2.10, N.A.)	41	18 (43.9)	6.87 (3.68, N.A.)	1.003 (0.521, 1.930) 0.9933	
REGION								0.2334
ASIA	116	26 (22.4)	N.A. (18.60, N.A.)	104	36 (34.6)	N.A. (7.43, N.A.)	0.518 (0.308, 0.874) 0.0121	
NON-ASIA	42	18 (42.9)	N.A. (2.10, N.A.)	41	18 (43.9)	6.87 (3.68, N.A.)	1.003 (0.521, 1.930) 0.9933	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 316 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.0154*
0	71	11 (15.5)	N.A. (18.60, N.A.)	69	25 (36.2)	N.A. (5.55, N.A.)	0.278 (0.129, 0.597) 0.0005	
1	87	33 (37.9)	N.A. (7.85, N.A.)	74	28 (37.8)	N.A. (5.49, N.A.)	1.024 (0.616, 1.701) 0.9253	
WEIGHT								0.8473
< 60 KG	96	25 (26.0)	N.A. (18.60, N.A.)	76	26 (34.2)	N.A. (5.55, N.A.)	0.649 (0.369, 1.141) 0.1294	
>= 60 KG	62	19 (30.6)	N.A.	69	28 (40.6)	8.61 (3.68, N.A.)	0.698 (0.388, 1.255) 0.2279	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 317 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9035
STAGE I	5	1 (20.0)	N.A. (12.98, N.A.)	5	1 (20.0)	N.A. (2.76, N.A.)	<0.001 (<0.001, N.A.) 0.3173	
STAGE II	5	1 (20.0)	N.A. (0.89, N.A.)	5	1 (20.0)	N.A. (0.92, N.A.)	0.894 (0.056, 14.358) 0.9372	
STAGE III	33	7 (21.2)	N.A. (8.38, N.A.)	46	17 (37.0)	N.A. (6.18, N.A.)	0.505 (0.209, 1.223) 0.1232	
STAGE IV	114	35 (30.7)	N.A. (18.60, N.A.)	89	35 (39.3)	8.61 (5.42, N.A.)	0.699 (0.433, 1.129) 0.1401	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 318 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9543
GX	11	1 (9.1)	N.A. (5.52, N.A.)	14	4 (28.6)	N.A. (1.94, N.A.)	0.341 (0.038, 3.054) 0.3131	
G1	8	4 (50.0)	10.68 (0.89, N.A.)	8	4 (50.0)	N.A. (0.07, N.A.)	0.625 (0.136, 2.872) 0.5424	
G2	58	17 (29.3)	N.A. (21.55, N.A.)	50	21 (42.0)	8.61 (4.44, N.A.)	0.647 (0.337, 1.241) 0.1853	
G3	28	9 (32.1)	N.A. (4.83, N.A.)	36	12 (33.3)	N.A. (4.30, N.A.)	0.863 (0.363, 2.053) 0.7393	
NOT OTHERWISE SPECIFIED	51	13 (25.5)	N.A. (18.60, N.A.)	37	13 (35.1)	N.A. (4.57, N.A.)	0.609 (0.275, 1.349) 0.2195	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 319 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.4854
UPPER THORACIC	37	8 (21.6)	N.A. (8.28, N.A.)	25	10 (40.0)	6.87 (2.10, N.A.)	0.433 (0.170, 1.105) 0.0717	
MIDDLE THORACIC	50	11 (22.0)	N.A. (8.28, N.A.)	52	20 (38.5)	N.A. (4.80, N.A.)	0.537 (0.251, 1.147) 0.1015	
LOWER THORACIC	59	20 (33.9)	N.A. (8.38, N.A.)	60	22 (36.7)	N.A. (3.61, N.A.)	0.759 (0.405, 1.424) 0.3907	
GASTROESOPHAGEAL JUNCTION	11	4 (36.4)	N.A. (0.39, N.A.)	8	2 (25.0)	N.A. (0.99, N.A.)	1.594 (0.292, 8.711) 0.5873	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 320 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9969
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	5 (38.5)	N.A. (0.92, N.A.)	N.E. 0.0452	
RECURRENT - DISTANT	25	7 (28.0)	12.98 (8.38, N.A.)	27	8 (29.6)	N.A. (6.18, N.A.)	0.671 (0.231, 1.945) 0.4591	
DE NOVO METASTATIC	107	33 (30.8)	N.A. (18.60, N.A.)	81	33 (40.7)	8.61 (4.57, N.A.)	0.665 (0.406, 1.090) 0.1027	
UNRESECTABLE ADVANCED	18	4 (22.2)	N.A.	24	8 (33.3)	N.A. (5.49, N.A.)	0.723 (0.217, 2.402) 0.5945	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 321 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6961
CURRENT/FORMER	136	38 (27.9)	N.A. (18.60, N.A.)	111	43 (38.7)	N.A. (5.42, N.A.)	0.630 (0.403, 0.984) 0.0404	
NEVER/UNKNOWN	22	6 (27.3)	N.A. (6.54, N.A.)	34	11 (32.4)	8.61 (5.49, N.A.)	0.777 (0.286, 2.110) 0.6202	
ALCOHOL USE								0.5496
CURRENT/FORMER	126	29 (23.0)	N.A. (21.55, N.A.)	117	39 (33.3)	N.A. (7.43, N.A.)	0.595 (0.363, 0.973) 0.0363	
NEVER/UNKNOWN	32	15 (46.9)	7.85 (2.33, N.A.)	28	15 (53.6)	5.49 (1.81, N.A.)	0.802 (0.388, 1.659) 0.5571	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 322 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.5511
<= 1	80	21 (26.3)	N.A. (18.60, N.A.)	69	27 (39.1)	N.A. (5.49, N.A.)	0.550 (0.304, 0.993) 0.0440	
>= 2	78	23 (29.5)	N.A. (8.38, N.A.)	76	27 (35.5)	N.A. (5.55, N.A.)	0.770 (0.440, 1.347) 0.3572	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.8197
< 1 YEAR	128	37 (28.9)	N.A. (18.60, N.A.)	115	46 (40.0)	8.61 (5.49, N.A.)	0.633 (0.406, 0.985) 0.0407	
1 - < 3 YEARS	25	6 (24.0)	N.A. (8.38, N.A.)	21	6 (28.6)	N.A. (2.76, N.A.)	0.785 (0.252, 2.446) 0.6814	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 323 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.8205
YES	38	8 (21.1)	N.A. (12.98, N.A.)	37	10 (27.0)	N.A.	0.585 (0.226, 1.511) 0.2635	
NO	120	36 (30.0)	N.A. (18.60, N.A.)	108	44 (40.7)	8.61 (5.49, N.A.)	0.673 (0.429, 1.055) 0.0817	
PRIOR RADIOTHERAPY								0.5865
YES	26	5 (19.2)	N.A.	27	9 (33.3)	N.A. (4.80, N.A.)	0.550 (0.184, 1.643) 0.2780	
NO	132	39 (29.5)	N.A. (18.60, N.A.)	118	45 (38.1)	N.A. (5.55, N.A.)	0.666 (0.429, 1.033) 0.0670	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 324 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.6620
< 10	53	16 (30.2)	N.A. (21.55, N.A.)	54	22 (40.7)	N.A. (2.20, N.A.)	0.623 (0.323, 1.201) 0.1526	
>= 10	92	24 (26.1)	N.A. (18.60, N.A.)	89	30 (33.7)	N.A. (6.18, N.A.)	0.717 (0.414, 1.241) 0.2326	
PD-L1 CPS II								0.6726
< 5	29	10 (34.5)	21.55 (1.87, N.A.)	24	12 (50.0)	N.A. (0.99, N.A.)	0.597 (0.251, 1.418) 0.2387	
>= 5	116	30 (25.9)	N.A. (18.60, N.A.)	119	40 (33.6)	N.A. (6.87, N.A.)	0.701 (0.433, 1.135) 0.1462	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 325 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.2201
< 10%	55	16 (29.1)	N.A. (21.55, N.A.)	57	26 (45.6)	7.43 (2.56, N.A.)	0.477 (0.251, 0.905) 0.0207	
>= 10%	103	28 (27.2)	N.A. (18.60, N.A.)	88	28 (31.8)	N.A. (6.87, N.A.)	0.812 (0.476, 1.382) 0.4418	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2312
< 5%	38	12 (31.6)	21.55 (6.54, N.A.)	41	21 (51.2)	5.55 (1.87, 8.61)	0.439 (0.210, 0.917) 0.0247	
>= 5%	120	32 (26.7)	N.A. (18.60, N.A.)	104	33 (31.7)	N.A.	0.792 (0.483, 1.297) 0.3526	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 326 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	2 (1.3)	N.A.	145	11 (7.6)	N.A.	0.135 (0.029, 0.632) 0.0034	
AGE								N.M.E.
< 65	95	1 (1.1)	N.M.E.	75	8 (10.7)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	1 (1.8)	N.M.E.	58	2 (3.4)	N.M.E.	N.M.E.	
>= 75	8	0	N.M.E.	12	1 (8.3)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 327 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9939
MALE	131	2 (1.5)	N.A.	122	9 (7.4)	N.A.	0.161 (0.033, 0.783) 0.0111	
FEMALE	27	0	N.E.	23	2 (8.7)	N.A.	N.E. 0.1213	
RACE								N.M.E.
ASIAN	117	1 (0.9)	N.M.E.	104	3 (2.9)	N.M.E.	N.M.E.	
NON-ASIAN	41	1 (2.4)	N.M.E.	41	8 (19.5)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 328 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	0	N.M.E.	85	2 (2.4)	N.M.E.	N.M.E.	
REST OF ASIA	25	1 (4.0)	N.M.E.	19	1 (5.3)	N.M.E.	N.M.E.	
REST OF WORLD	42	1 (2.4)	N.M.E.	41	8 (19.5)	N.M.E.	N.M.E.	
REGION								N.M.E.
ASIA	116	1 (0.9)	N.M.E.	104	3 (2.9)	N.M.E.	N.M.E.	
NON-ASIA	42	1 (2.4)	N.M.E.	41	8 (19.5)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 329 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	0	N.M.E.	69	4 (5.8)	N.M.E.	N.M.E.	
1	87	2 (2.3)	N.M.E.	74	6 (8.1)	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	1 (1.0)	N.M.E.	76	4 (5.3)	N.M.E.	N.M.E.	
>= 60 KG	62	1 (1.6)	N.M.E.	69	7 (10.1)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 330 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE II	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE III	33	1 (3.0)	N.M.E.	46	3 (6.5)	N.M.E.	N.M.E.	
STAGE IV	114	1 (0.9)	N.M.E.	89	8 (9.0)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 331 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	1 (7.1)	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	2 (3.4)	N.M.E.	50	5 (10.0)	N.M.E.	N.M.E.	
G3	28	0	N.M.E.	36	5 (13.9)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	0	N.M.E.	37	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 332 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	0	N.M.E.	25	1 (4.0)	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	0	N.M.E.	52	3 (5.8)	N.M.E.	N.M.E.	
LOWER THORACIC	59	0	N.M.E.	60	7 (11.7)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.M.E.	8	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 333 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	0	N.M.E.	27	1 (3.7)	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	1 (0.9)	N.M.E.	81	7 (8.6)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.M.E.	24	1 (4.2)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 334 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9922
CURRENT/FORMER	136	2 (1.5)	N.A.	111	9 (8.1)	N.A.	0.137 (0.028, 0.669) 0.0050	
NEVER/UNKNOWN	22	0	N.E.	34	2 (5.9)	N.A.	N.E. 0.2691	
ALCOHOL USE								0.1909
CURRENT/FORMER	126	1 (0.8)	N.A.	117	10 (8.5)	N.A.	0.089 (0.011, 0.693) 0.0036	
NEVER/UNKNOWN	32	1 (3.1)	N.A. (14.55, N.A.)	28	1 (3.6)	N.A.	0.425 (0.022, 8.293) 0.5648	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 335 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	2 (2.5)	N.M.E.	69	2 (2.9)	N.M.E.	N.M.E.	
>= 2	78	0	N.M.E.	76	9 (11.8)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9925
< 1 YEAR	128	2 (1.6)	N.A.	115	8 (7.0)	N.A.	0.174 (0.035, 0.862) 0.0174	
1 - < 3 YEARS	25	0	N.E.	21	3 (14.3)	N.A.	N.E. 0.0488	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 336 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9931
YES	38	0	N.E.	37	2 (5.4)	N.A.	N.E. 0.1456	
NO	120	2 (1.7)	N.A.	108	9 (8.3)	N.A.	0.161 (0.033, 0.775) 0.0104	
PRIOR RADIOTHERAPY								0.9915
YES	26	0	N.E.	27	3 (11.1)	N.A.	N.E. 0.0873	
NO	132	2 (1.5)	N.A.	118	8 (6.8)	N.A.	0.174 (0.035, 0.862) 0.0173	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 337 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	1 (1.9)	N.M.E.	54	4 (7.4)	N.M.E.	N.M.E.	
>= 10	92	1 (1.1)	N.M.E.	89	7 (7.9)	N.M.E.	N.M.E.	
PD-L1 CPS II								0.9938
< 5	29	0	N.E.	24	2 (8.3)	N.A.	N.E. 0.1295	
>= 5	116	2 (1.7)	N.A.	119	9 (7.6)	N.A.	0.187 (0.039, 0.895) 0.0201	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 338 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	1 (1.8)	N.M.E.	57	3 (5.3)	N.M.E.	N.M.E.	
>= 10%	103	1 (1.0)	N.M.E.	88	8 (9.1)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9934
< 5%	38	0	N.E.	41	2 (4.9)	N.A.	N.E.	
>= 5%	120	2 (1.7)	N.A.	104	9 (8.7)	N.A.	0.1632 0.156 (0.032, 0.753) 0.0090	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 339 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	47 (29.7)	N.A. (14.55, N.A.)	145	3 (2.1)	N.A.	16.778 (5.215, 53.980) <0.0001	
AGE								0.8791
< 65	95	26 (27.4)	N.A. (14.55, N.A.)	75	2 (2.7)	N.A.	11.787 (2.791, 49.779) <0.0001	
>= 65 AND < 75	55	18 (32.7)	9.66 (5.98, N.A.)	58	1 (1.7)	N.A.	23.196 (3.092,>99.999) <0.0001	
>= 75	8	3 (37.5)	N.A. (1.48, N.A.)	12	0	N.E.	N.E. 0.0244	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 340 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9902
MALE	131	40 (30.5)	16.76 (9.66, N.A.)	122	3 (2.5)	N.A.	14.379 (4.439, 46.581) <0.0001	
FEMALE	27	7 (25.9)	N.A.	23	0	N.E.	N.E. 0.0100	
RACE								0.8255
ASIAN	117	35 (29.9)	N.A. (8.38, N.A.)	104	2 (1.9)	N.A.	18.501 (4.447, 76.975) <0.0001	
NON-ASIAN	41	12 (29.3)	16.76 (6.01, N.A.)	41	1 (2.4)	N.A.	13.395 (1.725,>99.999) 0.0013	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 341 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9828
J/K/T	91	31 (34.1)	N.A. (5.75, N.A.)	85	2 (2.4)	N.A.	18.502 (4.423, 77.392) <0.0001	
REST OF ASIA	25	3 (12.0)	N.A.	19	0	N.E.	N.E. 0.1406	
REST OF WORLD	42	13 (31.0)	16.76 (6.01, N.A.)	41	1 (2.4)	N.A.	13.380 (1.732,>99.999) 0.0013	
REGION								0.8597
ASIA	116	34 (29.3)	N.A. (8.38, N.A.)	104	2 (1.9)	N.A.	18.252 (4.384, 75.991) <0.0001	
NON-ASIA	42	13 (31.0)	16.76 (6.01, N.A.)	41	1 (2.4)	N.A.	13.380 (1.732,>99.999) 0.0013	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 342 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.3967
0	71	26 (36.6)	N.A. (8.11, N.A.)	69	1 (1.4)	N.A.	29.286 (3.969,>99.999) <0.0001	
1	87	21 (24.1)	N.A. (9.66, N.A.)	74	2 (2.7)	N.A.	10.229 (2.387, 43.824) 0.0001	
WEIGHT								0.5389
< 60 KG	96	28 (29.2)	N.A. (9.66, N.A.)	76	1 (1.3)	N.A.	26.146 (3.554,>99.999) <0.0001	
>= 60 KG	62	19 (30.6)	16.76 (8.38, N.A.)	69	2 (2.9)	N.A.	12.007 (2.789, 51.688) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 343 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9950
STAGE I	5	2 (40.0)	N.A. (1.97, N.A.)	5	0	N.E.	N.E. 0.1343	
STAGE II	5	3 (60.0)	2.73 (1.81, N.A.)	5	0	N.E.	N.E. 0.1269	
STAGE III	33	12 (36.4)	16.76 (8.11, N.A.)	46	1 (2.2)	N.A.	16.527 (2.128,>99.999) 0.0003	
STAGE IV	114	30 (26.3)	N.A. (9.66, N.A.)	89	2 (2.2)	N.A.	14.320 (3.419, 59.980) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 344 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8711
GX	11	2 (18.2)	N.A. (2.76, N.A.)	14	0	N.E.	N.E. 0.0530	
G1	8	2 (25.0)	N.A. (2.73, N.A.)	8	0	N.E.	N.E. 0.1159	
G2	58	22 (37.9)	8.38 (5.75, N.A.)	50	1 (2.0)	N.A.	23.779 (3.202,>99.999) <0.0001	
G3	28	7 (25.0)	N.A. (9.66, N.A.)	36	0	N.E.	N.E. 0.0031	
NOT OTHERWISE SPECIFIED	51	14 (27.5)	N.A. (8.11, N.A.)	37	2 (5.4)	N.A. (7.69, N.A.)	5.886 (1.334, 25.972) 0.0080	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 345 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9406
UPPER THORACIC	37	16 (43.2)	8.11 (3.45, N.A.)	25	1 (4.0)	N.A.	12.813 (1.696, 96.821) 0.0014	
MIDDLE THORACIC	50	16 (32.0)	8.38 (5.98, N.A.)	52	1 (1.9)	N.A.	23.986 (3.165,>99.999) <0.0001	
LOWER THORACIC	59	9 (15.3)	N.A.	60	1 (1.7)	N.A.	10.000 (1.266, 78.981) 0.0070	
GASTROESOPHAGEAL JUNCTION	11	5 (45.5)	14.55 (1.45, N.A.)	8	0	N.E.	N.E. 0.1309	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 346 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9995
RECURRENT - LOCO-REGIONAL	8	3 (37.5)	16.76 (1.45, N.A.)	13	0	N.E.	N.E. 0.0572	
RECURRENT - DISTANT	25	9 (36.0)	N.A. (2.56, N.A.)	27	0	N.E.	N.E. 0.0007	
DE NOVO METASTATIC	107	26 (24.3)	N.A.	81	2 (2.5)	N.A.	12.303 (2.917, 51.889) <0.0001	
UNRESECTABLE ADVANCED	18	9 (50.0)	9.66 (2.73, N.A.)	24	1 (4.2)	N.A. (7.69, N.A.)	11.823 (1.490, 93.825) 0.0031	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 347 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.1672
CURRENT/FORMER	136	45 (33.1)	16.76 (8.38, N.A.)	111	2 (1.8)	N.A.	21.959 (5.318, 90.667) <0.0001	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	1 (2.9)	N.A.	3.193 (0.289, 35.216) 0.3164	
ALCOHOL USE								0.6117
CURRENT/FORMER	126	37 (29.4)	N.A. (9.66, N.A.)	117	2 (1.7)	N.A.	20.175 (4.856, 83.816) <0.0001	
NEVER/UNKNOWN	32	10 (31.3)	N.A. (2.92, N.A.)	28	1 (3.6)	N.A.	9.945 (1.263, 78.336) 0.0074	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 348 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.1683
<= 1	80	34 (42.5)	9.66 (4.47, N.A.)	69	1 (1.4)	N.A.	38.883 (5.318,>99.999) <0.0001	
>= 2	78	13 (16.7)	N.A. (16.76, N.A.)	76	2 (2.6)	N.A.	6.575 (1.468, 29.440) 0.0047	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9857
< 1 YEAR	128	35 (27.3)	N.A. (14.55, N.A.)	115	3 (2.6)	N.A.	12.186 (3.741, 39.692) <0.0001	
1 - < 3 YEARS	25	10 (40.0)	8.11 (2.73, N.A.)	21	0	N.E.	N.E. 0.0025	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 349 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9874
YES	38	13 (34.2)	N.A. (3.75, N.A.)	37	0	N.E.	N.E. 0.0002	
NO	120	34 (28.3)	N.A. (8.38, N.A.)	108	3 (2.8)	N.A.	12.026 (3.683, 39.269) <0.0001	
PRIOR RADIOTHERAPY								0.9895
YES	26	10 (38.5)	16.76 (2.73, N.A.)	27	0	N.E.	N.E. 0.0006	
NO	132	37 (28.0)	N.A. (14.55, N.A.)	118	3 (2.5)	N.A.	12.942 (3.984, 42.040) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 350 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.7453
< 10	53	19 (35.8)	8.38 (5.75, N.A.)	54	1 (1.9)	N.A.	24.291 (3.245,>99.999) <0.0001	
>= 10	92	27 (29.3)	N.A. (14.55, N.A.)	89	2 (2.2)	N.A.	14.854 (3.521, 62.666) <0.0001	
PD-L1 CPS II								0.9857
< 5	29	8 (27.6)	8.38 (6.01, N.A.)	24	0	N.E.	N.E. 0.0058	
>= 5	116	38 (32.8)	16.76 (9.66, N.A.)	119	3 (2.5)	N.A.	15.316 (4.717, 49.728) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 351 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.7848
< 10%	55	18 (32.7)	N.A. (8.11, N.A.)	57	1 (1.8)	N.A. (7.69, N.A.)	20.251 (2.698,>99.999) <0.0001	
>= 10%	103	29 (28.2)	N.A. (14.55, N.A.)	88	2 (2.3)	N.A.	14.606 (3.473, 61.427) <0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.8728
< 5%	38	12 (31.6)	N.A. (6.01, N.A.)	41	1 (2.4)	N.A.	14.097 (1.830,>99.999) 0.0008	
>= 5%	120	35 (29.2)	N.A. (9.66, N.A.)	104	2 (1.9)	N.A.	17.823 (4.277, 74.267) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 352 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	24 (15.2)	N.A.	145	0	N.E.	N.E. <0.0001	
AGE								>0.9999
< 65	95	16 (16.8)	N.A.	75	0	N.E.	N.E. 0.0002	
>= 65 AND < 75	55	7 (12.7)	N.A.	58	0	N.E.	N.E. 0.0050	
>= 75	8	1 (12.5)	N.A. (1.81, N.A.)	12	0	N.E.	N.E. 0.2410	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 353 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9999
MALE	131	21 (16.0)	N.A.	122	0	N.E.	N.E. <0.0001	
FEMALE	27	3 (11.1)	N.A.	23	0	N.E.	N.E. 0.1017	
RACE								>0.9999
ASIAN	117	17 (14.5)	N.A.	104	0	N.E.	N.E. <0.0001	
NON-ASIAN	41	7 (17.1)	N.A.	41	0	N.E.	N.E. 0.0044	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 354 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								>0.9999
J/K/T	91	16 (17.6)	N.A.	85	0	N.E.	N.E. <0.0001	
REST OF ASIA	25	1 (4.0)	N.A.	19	0	N.E.	N.E. 0.4250	
REST OF WORLD	42	7 (16.7)	N.A.	41	0	N.E.	N.E. 0.0051	
REGION								>0.9999
ASIA	116	17 (14.7)	N.A.	104	0	N.E.	N.E. <0.0001	
NON-ASIA	42	7 (16.7)	N.A.	41	0	N.E.	N.E. 0.0051	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 355 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								>0.9999
0	71	12 (16.9)	N.A.	69	0	N.E.	N.E. 0.0005	
1	87	12 (13.8)	N.A.	74	0	N.E.	N.E. 0.0007	
WEIGHT								>0.9999
< 60 KG	96	15 (15.6)	N.A.	76	0	N.E.	N.E. 0.0003	
>= 60 KG	62	9 (14.5)	N.A.	69	0	N.E.	N.E. 0.0014	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 356 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	1 (20.0)	N.A. (2.76, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	3 (60.0)	2.73 (1.81, N.A.)	5	0	N.E.	N.E. 0.1269	
STAGE III	33	6 (18.2)	N.A.	46	0	N.E.	N.E. 0.0036	
STAGE IV	114	14 (12.3)	N.A.	89	0	N.E.	N.E. 0.0005	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 357 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								>0.9999
GX	11	0	N.E.	14	0	N.E.	N.E. N.E.	
G1	8	2 (25.0)	N.A. (2.73, N.A.)	8	0	N.E.	N.E. 0.1159	
G2	58	13 (22.4)	N.A. (8.38, N.A.)	50	0	N.E.	N.E. 0.0005	
G3	28	2 (7.1)	N.A.	36	0	N.E.	N.E. 0.0807	
NOT OTHERWISE SPECIFIED	51	7 (13.7)	N.A.	37	0	N.E.	N.E. 0.0204	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 358 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	9 (24.3)	N.M.E.	25	0	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	8 (16.0)	N.M.E.	52	0	N.M.E.	N.M.E.	
LOWER THORACIC	59	6 (10.2)	N.M.E.	60	0	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.M.E.	8	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 359 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	0	N.E.	N.E. N.E.	
RECURRENT - DISTANT	25	8 (32.0)	N.A. (3.75, N.A.)	27	0	N.E.	N.E. 0.0017	
DE NOVO METASTATIC	107	12 (11.2)	N.A.	81	0	N.E.	N.E. 0.0015	
UNRESECTABLE ADVANCED	18	4 (22.2)	N.A. (8.38, N.A.)	24	0	N.E.	N.E. 0.0283	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 360 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9967
CURRENT/FORMER	136	24 (17.6)	N.A.	111	0	N.E.	N.E. <0.0001	
NEVER/UNKNOWN	22	0	N.E.	34	0	N.E.	N.E. N.E.	
ALCOHOL USE								>0.9999
CURRENT/FORMER	126	19 (15.1)	N.A.	117	0	N.E.	N.E. <0.0001	
NEVER/UNKNOWN	32	5 (15.6)	N.A.	28	0	N.E.	N.E. 0.0220	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 361 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9997
<= 1	80	19 (23.8)	N.A.	69	0	N.E.	N.E. <0.0001	
>= 2	78	5 (6.4)	N.A.	76	0	N.E.	N.E. 0.0337	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9998
< 1 YEAR	128	15 (11.7)	N.A.	115	0	N.E.	N.E. 0.0002	
1 - < 3 YEARS	25	7 (28.0)	N.A. (3.75, N.A.)	21	0	N.E.	N.E. 0.0108	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 362 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9998
YES	38	9 (23.7)	N.A.	37	0	N.E.	N.E. 0.0021	
NO	120	15 (12.5)	N.A.	108	0	N.E.	N.E. 0.0001	
PRIOR RADIOTHERAPY								0.9997
YES	26	8 (30.8)	N.A. (2.73, N.A.)	27	0	N.E.	N.E. 0.0016	
NO	132	16 (12.1)	N.A.	118	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 363 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								>0.9999
< 10	53	10 (18.9)	N.A. (8.38, N.A.)	54	0	N.E.	N.E. 0.0018	
>= 10	92	13 (14.1)	N.A.	89	0	N.E.	N.E. 0.0002	
PD-L1 CPS II								0.9999
< 5	29	6 (20.7)	N.A. (6.01, N.A.)	24	0	N.E.	N.E. 0.0242	
>= 5	116	17 (14.7)	N.A.	119	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 364 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								>0.9999
< 10%	55	9 (16.4)	N.A.	57	0	N.E.	N.E. 0.0045	
>= 10%	103	15 (14.6)	N.A.	88	0	N.E.	N.E. 0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								>0.9999
< 5%	38	6 (15.8)	N.A.	41	0	N.E.	N.E. 0.0157	
>= 5%	120	18 (15.0)	N.A.	104	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 365 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	13 (8.2)	N.A.	145	1 (0.7)	N.A.	13.190 (1.725,>99.999) 0.0012	
AGE								N.M.E.
< 65	95	6 (6.3)	N.M.E.	75	1 (1.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	7 (12.7)	N.M.E.	58	0	N.M.E.	N.M.E.	
>= 75	8	0	N.M.E.	12	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 366 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9918
MALE	131	10 (7.6)	N.A.	122	1 (0.8)	N.A.	10.360 (1.325, 80.996) 0.0056	
FEMALE	27	3 (11.1)	N.A.	23	0	N.E.	N.E. 0.1091	
RACE								N.M.E.
ASIAN	117	8 (6.8)	N.M.E.	104	0	N.M.E.	N.M.E.	
NON-ASIAN	41	5 (12.2)	N.M.E.	41	1 (2.4)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 367 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	7 (7.7)	N.M.E.	85	0	N.M.E.	N.M.E.	
REST OF ASIA	25	1 (4.0)	N.M.E.	19	0	N.M.E.	N.M.E.	
REST OF WORLD	42	5 (11.9)	N.M.E.	41	1 (2.4)	N.M.E.	N.M.E.	
REGION								N.M.E.
ASIA	116	8 (6.9)	N.M.E.	104	0	N.M.E.	N.M.E.	
NON-ASIA	42	5 (11.9)	N.M.E.	41	1 (2.4)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 368 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	6 (8.5)	N.M.E.	69	0	N.M.E.	N.M.E.	
1	87	7 (8.0)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	6 (6.3)	N.M.E.	76	0	N.M.E.	N.M.E.	
>= 60 KG	62	7 (11.3)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 369 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	3 (9.1)	N.A.	46	0	N.E.	N.E. 0.0362	
STAGE IV	114	10 (8.8)	N.A.	89	1 (1.1)	N.A.	8.920 (1.141, 69.754) 0.0116	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 370 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	1 (9.1)	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	5 (8.6)	N.M.E.	50	1 (2.0)	N.M.E.	N.M.E.	
G3	28	2 (7.1)	N.M.E.	36	0	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	5 (9.8)	N.M.E.	37	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 371 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	2 (5.4)	N.M.E.	25	1 (4.0)	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	5 (10.0)	N.M.E.	52	0	N.M.E.	N.M.E.	
LOWER THORACIC	59	2 (3.4)	N.M.E.	60	0	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	N.M.E.	8	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 372 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	N.A. (1.45, N.A.)	13	0	N.E.	N.E. 0.0684	
RECURRENT - DISTANT	25	1 (4.0)	N.A.	27	0	N.E.	N.E. 0.3074	
DE NOVO METASTATIC	107	9 (8.4)	N.A.	81	1 (1.2)	N.A.	7.831 (0.991, 61.893) 0.0208	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A.	24	0	N.E.	N.E. 0.2583	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 373 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9935
CURRENT/FORMER	136	11 (8.1)	N.A.	111	1 (0.9)	N.A.	9.824 (1.268, 76.148) 0.0071	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	0	N.E.	N.E. 0.0671	
ALCOHOL USE								0.9911
CURRENT/FORMER	126	9 (7.1)	N.A.	117	1 (0.9)	N.A.	9.103 (1.153, 71.898) 0.0109	
NEVER/UNKNOWN	32	4 (12.5)	N.A.	28	0	N.E.	N.E. 0.0431	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 374 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	7 (8.8)	N.M.E.	69	0	N.M.E.	N.M.E.	
>= 2	78	6 (7.7)	N.M.E.	76	1 (1.3)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9922
< 1 YEAR	128	10 (7.8)	N.A.	115	1 (0.9)	N.A.	10.078 (1.289, 78.789) 0.0065	
1 - < 3 YEARS	25	3 (12.0)	N.A.	21	0	N.E.	N.E. 0.1171	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 375 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9934
YES	38	3 (7.9)	N.A.	37	0	N.E.	N.E. 0.0905	
NO	120	10 (8.3)	N.A.	108	1 (0.9)	N.A.	10.253 (1.311, 80.177) 0.0059	
PRIOR RADIOTHERAPY								0.9944
YES	26	2 (7.7)	N.A.	27	0	N.E.	N.E. 0.1385	
NO	132	11 (8.3)	N.A.	118	1 (0.8)	N.A.	10.872 (1.403, 84.263) 0.0042	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 376 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	5 (9.4)	N.M.E.	54	1 (1.9)	N.M.E.	N.M.E.	
>= 10	92	8 (8.7)	N.M.E.	89	0	N.M.E.	N.M.E.	
PD-L1 CPS II								0.9993
< 5	29	0	N.E.	24	0	N.E.	N.E.	
>= 5	116	13 (11.2)	N.A.	119	1 (0.8)	N.A.	N.E. 14.950 (1.954,>99.999) 0.0005	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 377 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9919
< 10%	55	4 (7.3)	N.A.	57	0	N.E.	N.E. 0.0411	
>= 10%	103	9 (8.7)	N.A.	88	1 (1.1)	N.A.	8.920 (1.129, 70.488) 0.0120	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9992
< 5%	38	0	N.E.	41	0	N.E.	N.E. N.E.	
>= 5%	120	13 (10.8)	N.A.	104	1 (1.0)	N.A.	13.015 (1.701, 99.557) 0.0014	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 378 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	10 (6.3)	N.A.	145	1 (0.7)	N.A.	7.773 (0.985, 61.355) 0.0217	
AGE								N.M.E.
< 65	95	5 (5.3)	N.M.E.	75	1 (1.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	3 (5.5)	N.M.E.	58	0	N.M.E.	N.M.E.	
>= 75	8	2 (25.0)	N.M.E.	12	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 379 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9954
MALE	131	9 (6.9)	N.A.	122	1 (0.8)	N.A.	6.759 (0.845, 54.059) 0.0377	
FEMALE	27	1 (3.7)	N.A.	23	0	N.E.	N.E. 0.3688	
RACE								N.M.E.
ASIAN	117	8 (6.8)	N.M.E.	104	1 (1.0)	N.M.E.	N.M.E.	
NON-ASIAN	41	2 (4.9)	N.M.E.	41	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 380 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	7 (7.7)	N.M.E.	85	1 (1.2)	N.M.E.	N.M.E.	
REST OF ASIA	25	1 (4.0)	N.M.E.	19	0	N.M.E.	N.M.E.	
REST OF WORLD	42	2 (4.8)	N.M.E.	41	0	N.M.E.	N.M.E.	
REGION								N.M.E.
ASIA	116	8 (6.9)	N.M.E.	104	1 (1.0)	N.M.E.	N.M.E.	
NON-ASIA	42	2 (4.8)	N.M.E.	41	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
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Protocol: CA209648 Page 381 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	6 (8.5)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
1	87	4 (4.6)	N.M.E.	74	0	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	5 (5.2)	N.M.E.	76	1 (1.3)	N.M.E.	N.M.E.	
>= 60 KG	62	5 (8.1)	N.M.E.	69	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 382 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE II	5	1 (20.0)	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE III	33	1 (3.0)	N.M.E.	46	1 (2.2)	N.M.E.	N.M.E.	
STAGE IV	114	8 (7.0)	N.M.E.	89	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 383 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	7 (12.1)	N.M.E.	50	0	N.M.E.	N.M.E.	
G3	28	1 (3.6)	N.M.E.	36	0	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	2 (3.9)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 384 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	1 (2.7)	N.M.E.	25	0	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	6 (12.0)	N.M.E.	52	1 (1.9)	N.M.E.	N.M.E.	
LOWER THORACIC	59	2 (3.4)	N.M.E.	60	0	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	0	N.M.E.	8	0	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 385 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	1 (12.5)	N.M.E.	13	0	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	1 (4.0)	N.M.E.	27	0	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	7 (6.5)	N.M.E.	81	0	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.M.E.	24	1 (4.2)	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
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(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 386 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9995
CURRENT/FORMER	136	10 (7.4)	N.A.	111	1 (0.9)	N.A.	6.920 (0.876, 54.657) 0.0333	
NEVER/UNKNOWN	22	0	N.E.	34	0	N.E.	N.E. N.E.	
ALCOHOL USE								0.9995
CURRENT/FORMER	126	10 (7.9)	N.A.	117	1 (0.9)	N.A.	8.110 (1.029, 63.898) 0.0181	
NEVER/UNKNOWN	32	0	N.E.	28	0	N.E.	N.E. N.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 387 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	6 (7.5)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
>= 2	78	4 (5.1)	N.M.E.	76	0	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								N.M.E.
< 1 YEAR	128	8 (6.3)	N.M.E.	115	1 (0.9)	N.M.E.	N.M.E.	
1 - < 3 YEARS	25	1 (4.0)	N.M.E.	21	0	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 388 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9946
YES	38	1 (2.6)	N.A.	37	0	N.E.	N.E. 0.3308	
NO	120	9 (7.5)	N.A.	108	1 (0.9)	N.A.	6.755 (0.843, 54.098) 0.0377	
PRIOR RADIOTHERAPY								N.M.E.
YES	26	2 (7.7)	N.M.E.	27	0	N.M.E.	N.M.E.	
NO	132	8 (6.1)	N.M.E.	118	1 (0.8)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
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Protocol: CA209648 Page 389 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	5 (9.4)	N.M.E.	54	0	N.M.E.	N.M.E.	
>= 10	92	5 (5.4)	N.M.E.	89	1 (1.1)	N.M.E.	N.M.E.	
PD-L1 CPS II								N.M.E.
< 5	29	2 (6.9)	N.M.E.	24	0	N.M.E.	N.M.E.	
>= 5	116	8 (6.9)	N.M.E.	119	1 (0.8)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 390 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	6 (10.9)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	
>= 10%	103	4 (3.9)	N.M.E.	88	0	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								N.M.E.
< 5%	38	3 (7.9)	N.M.E.	41	1 (2.4)	N.M.E.	N.M.E.	
>= 5%	120	7 (5.8)	N.M.E.	104	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 391 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	36 (22.8)	N.A. (24.94, N.A.)	145	59 (40.7)	9.17 (5.95, N.A.)	0.437 (0.285, 0.670) <0.0001	
AGE								0.3605
< 65	95	25 (26.3)	N.A. (8.15, N.A.)	75	30 (40.0)	9.17 (5.68, N.A.)	0.547 (0.318, 0.942) 0.0272	
>= 65 AND < 75	55	9 (16.4)	N.A.	58	24 (41.4)	6.70 (3.81, N.A.)	0.336 (0.156, 0.724) 0.0035	
>= 75	8	2 (25.0)	20.34 (5.29, N.A.)	12	5 (41.7)	5.95 (0.10, N.A.)	0.213 (0.025, 1.843) 0.1227	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 392 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4680
MALE	131	30 (22.9)	N.A. (20.34, N.A.)	122	52 (42.6)	7.29 (5.68, N.A.)	0.396 (0.248, 0.631) <0.0001	
FEMALE	27	6 (22.2)	N.A.	23	7 (30.4)	N.A. (4.80, N.A.)	0.745 (0.250, 2.219) 0.5950	
RACE								0.8038
ASIAN	117	26 (22.2)	N.A. (20.34, N.A.)	104	43 (41.3)	9.17 (5.95, N.A.)	0.423 (0.257, 0.696) 0.0005	
NON-ASIAN	41	10 (24.4)	24.94 (24.94, N.A.)	41	16 (39.0)	7.16 (4.50, N.A.)	0.498 (0.217, 1.144) 0.0944	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 393 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.5341
J/K/T	91	20 (22.0)	N.A. (20.34, N.A.)	85	38 (44.7)	7.29 (5.95, N.A.)	0.372 (0.213, 0.650) 0.0003	
REST OF ASIA	25	6 (24.0)	N.A. (6.47, N.A.)	19	5 (26.3)	N.A. (1.18, N.A.)	0.860 (0.262, 2.821) 0.8035	
REST OF WORLD	42	10 (23.8)	24.94 (24.94, N.A.)	41	16 (39.0)	7.16 (4.50, N.A.)	0.480 (0.209, 1.104) 0.0782	
REGION								0.8944
ASIA	116	26 (22.4)	N.A. (20.34, N.A.)	104	43 (41.3)	9.17 (5.95, N.A.)	0.429 (0.261, 0.706) 0.0006	
NON-ASIA	42	10 (23.8)	24.94 (24.94, N.A.)	41	16 (39.0)	7.16 (4.50, N.A.)	0.480 (0.209, 1.104) 0.0782	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 394 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.0200*
0	71	24 (33.8)	20.34 (7.13, N.A.)	69	27 (39.1)	10.22 (6.01, N.A.)	0.700 (0.400, 1.224) 0.2101	
1	87	12 (13.8)	N.A. (24.94, N.A.)	74	31 (41.9)	7.29 (4.73, N.A.)	0.246 (0.122, 0.495) <0.0001	
WEIGHT								0.4418
< 60 KG	96	20 (20.8)	N.A. (20.34, N.A.)	76	26 (34.2)	9.17 (6.70, N.A.)	0.506 (0.278, 0.920) 0.0229	
>= 60 KG	62	16 (25.8)	N.A. (8.15, N.A.)	69	33 (47.8)	5.68 (2.99, N.A.)	0.405 (0.219, 0.751) 0.0031	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 395 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8844
STAGE I	5	1 (20.0)	N.A. (5.09, N.A.)	5	2 (40.0)	7.29 (2.46, N.A.)	0.395 (0.036, 4.388) 0.4335	
STAGE II	5	1 (20.0)	N.A. (1.41, N.A.)	5	2 (40.0)	N.A. (0.03, N.A.)	0.334 (0.029, 3.845) 0.3578	
STAGE III	33	5 (15.2)	N.A. (7.13, N.A.)	46	16 (34.8)	6.70 (5.95, N.A.)	0.319 (0.116, 0.878) 0.0201	
STAGE IV	114	28 (24.6)	N.A. (20.34, N.A.)	89	39 (43.8)	9.17 (4.63, N.A.)	0.442 (0.267, 0.731) 0.0011	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 396 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9110
GX	11	2 (18.2)	N.A. (0.49, N.A.)	14	7 (50.0)	4.73 (0.95, N.A.)	0.397 (0.081, 1.944) 0.2389	
G1	8	0	N.E.	8	5 (62.5)	3.20 (0.89, N.A.)	N.E. 0.0116	
G2	58	15 (25.9)	N.A. (20.34, N.A.)	50	21 (42.0)	9.17 (3.65, N.A.)	0.481 (0.244, 0.950) 0.0313	
G3	28	5 (17.9)	N.A. (24.94, N.A.)	36	13 (36.1)	N.A. (5.09, N.A.)	0.364 (0.118, 1.121) 0.0664	
NOT OTHERWISE SPECIFIED	51	13 (25.5)	N.A. (7.13, N.A.)	37	13 (35.1)	10.22 (5.95, N.A.)	0.570 (0.262, 1.243) 0.1520	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 397 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8412
UPPER THORACIC	37	8 (21.6)	N.A. (7.89, N.A.)	25	9 (36.0)	7.16 (6.70, N.A.)	0.361 (0.133, 0.977) 0.0375	
MIDDLE THORACIC	50	11 (22.0)	N.A. (6.64, N.A.)	52	20 (38.5)	9.17 (4.73, N.A.)	0.532 (0.249, 1.140) 0.0992	
LOWER THORACIC	59	15 (25.4)	N.A. (24.94, N.A.)	60	28 (46.7)	6.01 (2.99, N.A.)	0.424 (0.223, 0.808) 0.0073	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A.	8	2 (25.0)	N.A. (0.16, N.A.)	0.373 (0.034, 4.116) 0.4020	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 398 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9850
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	6 (46.2)	6.70 (2.46, N.A.)	N.E. 0.0071	
RECURRENT - DISTANT	25	6 (24.0)	N.A. (5.68, N.A.)	27	10 (37.0)	N.A. (2.99, N.A.)	0.540 (0.196, 1.490) 0.2268	
DE NOVO METASTATIC	107	27 (25.2)	24.94 (20.34, N.A.)	81	35 (43.2)	7.16 (4.11, N.A.)	0.471 (0.280, 0.791) 0.0036	
UNRESECTABLE ADVANCED	18	3 (16.7)	N.A. (6.47, N.A.)	24	8 (33.3)	9.17 (5.95, N.A.)	0.347 (0.089, 1.348) 0.1104	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 399 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.7078
CURRENT/FORMER	136	30 (22.1)	N.A. (20.34, N.A.)	111	45 (40.5)	7.29 (5.68, N.A.)	0.428 (0.267, 0.686) 0.0003	
NEVER/UNKNOWN	22	6 (27.3)	N.A. (24.94, N.A.)	34	14 (41.2)	9.17 (2.99, N.A.)	0.503 (0.180, 1.411) 0.1810	
ALCOHOL USE								0.8730
CURRENT/FORMER	126	30 (23.8)	N.A. (20.34, N.A.)	117	49 (41.9)	7.16 (5.68, N.A.)	0.457 (0.287, 0.725) 0.0007	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (24.94, N.A.)	28	10 (35.7)	9.17 (4.73, N.A.)	0.341 (0.112, 1.035) 0.0478	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 400 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.1554
<= 1	80	25 (31.3)	24.94 (20.34, N.A.)	69	32 (46.4)	6.70 (4.80, 10.22)	0.543 (0.316, 0.933) 0.0247	
>= 2	78	11 (14.1)	N.A.	76	27 (35.5)	N.A. (5.09, N.A.)	0.312 (0.153, 0.636) 0.0008	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3965
< 1 YEAR	128	33 (25.8)	N.A. (20.34, N.A.)	115	49 (42.6)	7.16 (5.09, N.A.)	0.480 (0.304, 0.757) 0.0013	
1 - < 3 YEARS	25	3 (12.0)	N.A.	21	7 (33.3)	7.29 (2.00, N.A.)	0.290 (0.075, 1.125) 0.0569	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 401 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.7008
YES	38	9 (23.7)	N.A. (7.82, N.A.)	37	16 (43.2)	7.29 (3.42, N.A.)	0.394 (0.172, 0.901) 0.0225	
NO	120	27 (22.5)	N.A. (20.34, N.A.)	108	43 (39.8)	9.17 (5.68, N.A.)	0.461 (0.280, 0.758) 0.0018	
PRIOR RADIOTHERAPY								0.2920
YES	26	2 (7.7)	N.A.	27	8 (29.6)	10.22 (4.80, N.A.)	0.204 (0.043, 0.975) 0.0282	
NO	132	34 (25.8)	N.A. (20.34, N.A.)	118	51 (43.2)	7.16 (5.09, N.A.)	0.470 (0.301, 0.735) 0.0007	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 402 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.1174
< 10	53	14 (26.4)	N.A. (7.82, N.A.)	54	15 (27.8)	N.A. (5.68, N.A.)	0.782 (0.368, 1.659) 0.5200	
>= 10	92	20 (21.7)	N.A.	89	42 (47.2)	7.16 (4.73, 10.22)	0.381 (0.222, 0.653) 0.0003	
PD-L1 CPS II								0.6791
< 5	29	6 (20.7)	N.A. (20.34, N.A.)	24	7 (29.2)	N.A. (5.68, N.A.)	0.610 (0.193, 1.923) 0.3928	
>= 5	116	28 (24.1)	N.A.	119	50 (42.0)	7.29 (5.95, N.A.)	0.474 (0.297, 0.756) 0.0014	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 403 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.6091
< 10%	55	13 (23.6)	N.A. (20.34, N.A.)	57	20 (35.1)	N.A. (4.80, N.A.)	0.520 (0.252, 1.074) 0.0723	
>= 10%	103	23 (22.3)	N.A. (24.94, N.A.)	88	39 (44.3)	7.29 (5.95, N.A.)	0.410 (0.242, 0.694) 0.0006	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9975
< 5%	38	9 (23.7)	20.34 (7.82, N.A.)	41	16 (39.0)	N.A. (4.50, N.A.)	0.422 (0.179, 0.997) 0.0425	
>= 5%	120	27 (22.5)	N.A. (24.94, N.A.)	104	43 (41.3)	9.17 (6.01, N.A.)	0.448 (0.274, 0.732) 0.0010	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 404 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	3 (1.9)	N.A.	145	11 (7.6)	N.A.	0.227 (0.062, 0.824) 0.0142	
AGE								N.M.E.
< 65	95	1 (1.1)	N.M.E.	75	5 (6.7)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	2 (3.6)	N.M.E.	58	5 (8.6)	N.M.E.	N.M.E.	
>= 75	8	0	N.M.E.	12	1 (8.3)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 405 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9938
MALE	131	3 (2.3)	N.A.	122	10 (8.2)	N.A.	0.248 (0.067, 0.918) 0.0245	
FEMALE	27	0	N.E.	23	1 (4.3)	N.A.	N.E. 0.3173	
RACE								0.5045
ASIAN	117	2 (1.7)	N.A.	104	9 (8.7)	N.A.	0.169 (0.036, 0.795) 0.0112	
NON-ASIAN	41	1 (2.4)	N.A.	41	2 (4.9)	N.A.	0.540 (0.049, 5.958) 0.6094	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 406 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.8475
J/K/T	91	2 (2.2)	N.A. (10.22, N.A.)	85	9 (10.6)	N.A.	0.186 (0.039, 0.873) 0.0175	
REST OF ASIA	25	0	N.E.	19	0	N.E.	N.E. N.E.	
REST OF WORLD	42	1 (2.4)	N.A.	41	2 (4.9)	N.A.	0.523 (0.047, 5.771) 0.5903	
REGION								0.5322
ASIA	116	2 (1.7)	N.A.	104	9 (8.7)	N.A.	0.172 (0.037, 0.809) 0.0122	
NON-ASIA	42	1 (2.4)	N.A.	41	2 (4.9)	N.A.	0.523 (0.047, 5.771) 0.5903	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 407 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9932
0	71	3 (4.2)	N.A.	69	7 (10.1)	N.A. (10.22, N.A.)	0.359 (0.092, 1.402) 0.1245	
1	87	0	N.E.	74	4 (5.4)	N.A.	N.E. 0.0358	
WEIGHT								N.M.E.
< 60 KG	96	2 (2.1)	N.M.E.	76	6 (7.9)	N.M.E.	N.M.E.	
>= 60 KG	62	1 (1.6)	N.M.E.	69	5 (7.2)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 408 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	
STAGE II	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE III	33	1 (3.0)	N.M.E.	46	3 (6.5)	N.M.E.	N.M.E.	
STAGE IV	114	2 (1.8)	N.M.E.	89	7 (7.9)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	1 (7.1)	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	3 (37.5)	N.M.E.	N.M.E.	
G2	58	0	N.M.E.	50	2 (4.0)	N.M.E.	N.M.E.	
G3	28	1 (3.6)	N.M.E.	36	2 (5.6)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	2 (3.9)	N.M.E.	37	3 (8.1)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 410 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	0	N.M.E.	25	3 (12.0)	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	2 (4.0)	N.M.E.	52	5 (9.6)	N.M.E.	N.M.E.	
LOWER THORACIC	59	1 (1.7)	N.M.E.	60	2 (3.3)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
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Protocol: CA209648 Page 411 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	0	N.M.E.	13	1 (7.7)	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	1 (4.0)	N.M.E.	27	4 (14.8)	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	2 (1.9)	N.M.E.	81	6 (7.4)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	0	N.M.E.	24	0	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 412 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9921
CURRENT/FORMER	136	3 (2.2)	N.A.	111	10 (9.0)	N.A.	0.220 (0.060, 0.814) 0.0133	
NEVER/UNKNOWN	22	0	N.E.	34	1 (2.9)	N.A.	N.E. 0.3819	
ALCOHOL USE								0.9935
CURRENT/FORMER	126	3 (2.4)	N.A.	117	10 (8.5)	N.A.	0.248 (0.067, 0.917) 0.0244	
NEVER/UNKNOWN	32	0	N.E.	28	1 (3.6)	N.A.	N.E. 0.3173	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 413 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	1 (1.3)	N.M.E.	69	7 (10.1)	N.M.E.	N.M.E.	
>= 2	78	2 (2.6)	N.M.E.	76	4 (5.3)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.6555
< 1 YEAR	128	2 (1.6)	N.A.	115	8 (7.0)	N.A.	0.231 (0.049, 1.090) 0.0435	
1 - < 3 YEARS	25	1 (4.0)	N.A.	21	2 (9.5)	N.A. (7.29, N.A.)	0.402 (0.036, 4.438) 0.4416	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 414 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								N.M.E.
YES	38	1 (2.6)	N.M.E.	37	5 (13.5)	N.M.E.	N.M.E.	
NO	120	2 (1.7)	N.M.E.	108	6 (5.6)	N.M.E.	N.M.E.	
PRIOR RADIOTHERAPY								0.9944
YES	26	0	N.E.	27	1 (3.7)	N.A. (10.22, N.A.)	N.E. 0.1967	
NO	132	3 (2.3)	N.A.	118	10 (8.5)	N.A.	0.268 (0.074, 0.977) 0.0322	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 415 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	1 (1.9)	N.M.E.	54	4 (7.4)	N.M.E.	N.M.E.	
>= 10	92	2 (2.2)	N.M.E.	89	7 (7.9)	N.M.E.	N.M.E.	
PD-L1 CPS II								0.9939
< 5	29	0	N.E.	24	1 (4.2)	N.A.	N.E. 0.3173	
>= 5	116	3 (2.6)	N.A.	119	10 (8.4)	N.A.	0.276 (0.075, 1.017) 0.0392	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 416 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders. PT: Peripheral Sensory Neuropathy

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	1 (1.8)	N.M.E.	57	5 (8.8)	N.M.E.	N.M.E.	
>= 10%	103	2 (1.9)	N.M.E.	88	6 (6.8)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								N.M.E.
< 5%	38	1 (2.6)	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	
>= 5%	120	2 (1.7)	N.M.E.	104	7 (6.7)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 417 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	17 (10.8)	N.A.	145	5 (3.4)	N.A.	2.729 (0.993, 7.496) 0.0430	
AGE								0.9999
< 65	95	8 (8.4)	N.A.	75	5 (6.7)	N.A.	1.159 (0.376, 3.570) 0.7981	
>= 65 AND < 75	55	8 (14.5)	N.A.	58	0	N.E.	N.E. 0.0036	
>= 75	8	1 (12.5)	N.A. (17.12, N.A.)	12	0	N.E.	N.E. N.A.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 418 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9921
MALE	131	13 (9.9)	N.A.	122	5 (4.1)	N.A.	1.962 (0.684, 5.628) 0.2023	
FEMALE	27	4 (14.8)	N.A.	23	0	N.E.	N.E. 0.0572	
RACE								0.9685
ASIAN	117	14 (12.0)	N.A.	104	4 (3.8)	N.A. (8.18, N.A.)	2.804 (0.910, 8.634) 0.0610	
NON-ASIAN	41	3 (7.3)	N.A.	41	1 (2.4)	N.A.	2.145 (0.212, 21.691) 0.5090	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 419 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.2107
J/K/T	91	10 (11.0)	N.A.	85	1 (1.2)	N.A.	8.781 (1.113, 69.298) 0.0130	
REST OF ASIA	25	4 (16.0)	N.A. (12.98, N.A.)	19	3 (15.8)	N.A. (7.16, N.A.)	0.755 (0.152, 3.745) 0.7297	
REST OF WORLD	42	3 (7.1)	N.A.	41	1 (2.4)	N.A. (8.18, N.A.)	2.052 (0.202, 20.856) 0.5358	
REGION								0.9395
ASIA	116	14 (12.1)	N.A.	104	4 (3.8)	N.A.	2.835 (0.920, 8.729) 0.0581	
NON-ASIA	42	3 (7.1)	N.A.	41	1 (2.4)	N.A. (8.18, N.A.)	2.052 (0.202, 20.856) 0.5358	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 420 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6454
0	71	8 (11.3)	N.A. (17.12, N.A.)	69	2 (2.9)	N.A.	3.342 (0.700, 15.948) 0.1091	
1	87	9 (10.3)	N.A.	74	3 (4.1)	N.A.	2.272 (0.600, 8.608) 0.2156	
WEIGHT								0.3303
< 60 KG	96	9 (9.4)	N.A. (17.12, N.A.)	76	1 (1.3)	N.A.	5.370 (0.665, 43.360) 0.0778	
>= 60 KG	62	8 (12.9)	N.A.	69	4 (5.8)	N.A.	2.351 (0.706, 7.833) 0.1518	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 421 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (1) (mon)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (1) (mon)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.5292
STAGE I	5	1 (20.0)	N.A. (12.98, N.A.)	5	0	N.E.	N.E. 0.4795	
STAGE II	5	1 (20.0)	N.A. (2.63, N.A.)	5	2 (40.0)	N.A. (0.30, N.A.)	0.389 (0.035, 4.337) 0.4261	
STAGE III	33	2 (6.1)	N.A. (12.32, N.A.)	46	0	N.E.	N.E. 0.1982	
STAGE IV	114	13 (11.4)	N.A.	89	3 (3.4)	N.A.	3.142 (0.884, 11.173) 0.0626	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 422 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8945
GX	11	0	N.E.	14	0	N.E.	N.E. N.E.	
G1	8	1 (12.5)	N.A. (12.98, N.A.)	8	0	N.E.	N.E. N.A.	
G2	58	10 (17.2)	N.A. (17.12, N.A.)	50	2 (4.0)	N.A.	4.030 (0.876, 18.536) 0.0532	
G3	28	2 (7.1)	N.A.	36	2 (5.6)	N.A.	1.049 (0.144, 7.628) 0.9624	
NOT OTHERWISE SPECIFIED	51	4 (7.8)	N.A.	37	1 (2.7)	N.A.	3.136 (0.350, 28.060) 0.2816	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 423 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.8583
UPPER THORACIC	37	2 (5.4)	N.A.	25	1 (4.0)	N.A.	1.372 (0.124, 15.130) 0.7955	
MIDDLE THORACIC	50	7 (14.0)	N.A. (17.12, N.A.)	52	0	N.E.	N.E. 0.0089	
LOWER THORACIC	59	7 (11.9)	N.A.	60	3 (5.0)	N.A.	2.001 (0.501, 7.997) 0.3185	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (12.32, N.A.)	8	1 (12.5)	8.18 (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0455	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 424 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9592
RECURRENT - LOCO-REGIONAL	8	1 (12.5)	N.A. (0.69, N.A.)	13	1 (7.7)	N.A.	1.561 (0.098, 24.974) 0.7508	
RECURRENT - DISTANT	25	2 (8.0)	N.A. (12.98, N.A.)	27	1 (3.7)	N.A.	1.108 (0.069, 17.718) 0.9423	
DE NOVO METASTATIC	107	13 (12.1)	N.A.	81	3 (3.7)	N.A.	3.055 (0.859, 10.866) 0.0702	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A. (12.32, N.A.)	24	0	N.E.	N.E. 0.4386	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 425 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9907
CURRENT/FORMER	136	15 (11.0)	N.A.	111	5 (4.5)	N.A.	2.034 (0.725, 5.706) 0.1691	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	0	N.E.	N.E. 0.0602	
ALCOHOL USE								0.9915
CURRENT/FORMER	126	12 (9.5)	N.A.	117	5 (4.3)	N.A.	2.041 (0.710, 5.867) 0.1765	
NEVER/UNKNOWN	32	5 (15.6)	N.A. (12.32, N.A.)	28	0	N.E.	N.E. 0.0495	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 426 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.6746
<= 1	80	12 (15.0)	N.A. (17.12, N.A.)	69	3 (4.3)	N.A.	3.135 (0.872, 11.267) 0.0654	
>= 2	78	5 (6.4)	N.A.	76	2 (2.6)	N.A.	2.007 (0.379, 10.633) 0.4042	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.0971
< 1 YEAR	128	14 (10.9)	N.A.	115	3 (2.6)	N.A.	3.632 (1.026, 12.849) 0.0329	
1 - < 3 YEARS	25	1 (4.0)	N.A.	21	2 (9.5)	N.A.	0.406 (0.037, 4.477) 0.4438	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 427 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9326
YES	38	3 (7.9)	N.A. (12.98, N.A.)	37	1 (2.7)	N.A.	2.402 (0.243, 23.729) 0.4381	
NO	120	14 (11.7)	N.A.	108	4 (3.7)	N.A.	2.778 (0.900, 8.578) 0.0645	
PRIOR RADIOTHERAPY								0.7401
YES	26	2 (7.7)	N.A.	27	1 (3.7)	N.A.	2.148 (0.195, 23.726) 0.5226	
NO	132	15 (11.4)	N.A.	118	4 (3.4)	N.A.	2.826 (0.921, 8.672) 0.0585	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 428 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.5848
< 10	53	4 (7.5)	N.A. (17.12, N.A.)	54	2 (3.7)	N.A. (8.18, N.A.)	1.327 (0.226, 7.783) 0.7534	
>= 10	92	11 (12.0)	N.A.	89	3 (3.4)	N.A.	3.374 (0.931, 12.232) 0.0501	
PD-L1 CPS II								0.9931
< 5	29	2 (6.9)	N.A. (17.12, N.A.)	24	0	N.E.	N.E. 0.3458	
>= 5	116	13 (11.2)	N.A.	119	5 (4.2)	N.A.	2.492 (0.880, 7.056) 0.0759	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 429 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3400
< 10%	55	3 (5.5)	N.A. (17.12, N.A.)	57	2 (3.5)	N.A.	1.039 (0.164, 6.582) 0.9676	
>= 10%	103	14 (13.6)	N.A.	88	3 (3.4)	N.A.	3.877 (1.104, 13.610) 0.0230	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7520
< 5%	38	2 (5.3)	N.A. (17.12, N.A.)	41	1 (2.4)	N.A. (8.18, N.A.)	1.333 (0.117, 15.177) 0.8165	
>= 5%	120	15 (12.5)	N.A.	104	4 (3.8)	N.A.	3.083 (1.014, 9.373) 0.0370	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 430 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
OVERALL	158	10 (6.3)	N.A.	145	1 (0.7)	N.A.	7.673 (0.967, 60.882) 0.0235	
AGE								N.M.E.
< 65	95	3 (3.2)	N.M.E.	75	1 (1.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	6 (10.9)	N.M.E.	58	0	N.M.E.	N.M.E.	
>= 75	8	1 (12.5)	N.M.E.	12	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 431 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	131	8 (6.1)	N.M.E.	122	1 (0.8)	N.M.E.	N.M.E.	
FEMALE	27	2 (7.4)	N.M.E.	23	0	N.M.E.	N.M.E.	
RACE								0.9945
ASIAN	117	9 (7.7)	N.A.	104	1 (1.0)	N.A.	7.147 (0.894, 57.148) 0.0307	
NON-ASIAN	41	1 (2.4)	N.A. (12.32, N.A.)	41	0	N.E.	N.E. 0.5839	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 432 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	7 (7.7)	N.M.E.	85	1 (1.2)	N.M.E.	N.M.E.	
REST OF ASIA	25	2 (8.0)	N.M.E.	19	0	N.M.E.	N.M.E.	
REST OF WORLD	42	1 (2.4)	N.M.E.	41	0	N.M.E.	N.M.E.	
REGION								0.9946
ASIA	116	9 (7.8)	N.A.	104	1 (1.0)	N.A.	7.228 (0.904, 57.783) 0.0294	
NON-ASIA	42	1 (2.4)	N.A.	41	0	N.E.	N.E. 0.6015	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 433 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	5 (7.0)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
1	87	5 (5.7)	N.M.E.	74	0	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	5 (5.2)	N.M.E.	76	0	N.M.E.	N.M.E.	
>= 60 KG	62	5 (8.1)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 434 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	1 (3.0)	N.A. (12.32, N.A.)	46	0	N.E.	N.E. 0.5403	
STAGE IV	114	9 (7.9)	N.A.	89	1 (1.1)	N.A.	6.337 (0.791, 50.779) 0.0467	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 435 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	6 (10.3)	N.M.E.	50	0	N.M.E.	N.M.E.	
G3	28	1 (3.6)	N.M.E.	36	0	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	3 (5.9)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 436 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	1 (2.7)	N.M.E.	25	0	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	2 (4.0)	N.M.E.	52	0	N.M.E.	N.M.E.	
LOWER THORACIC	59	6 (10.2)	N.M.E.	60	1 (1.7)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.M.E.	8	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 437 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	0	N.E.	N.E. N.E.	
RECURRENT - DISTANT	25	0	N.E.	27	0	N.E.	N.E. N.E.	
DE NOVO METASTATIC	107	9 (8.4)	N.A.	81	1 (1.2)	N.A.	6.151 (0.767, 49.316) 0.0514	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A. (12.32, N.A.)	24	0	N.E.	N.E. 0.4386	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 438 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
SMOKING STATUS								N.M.E.
CURRENT/FORMER	136	8 (5.9)	N.M.E.	111	1 (0.9)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	22	2 (9.1)	N.M.E.	34	0	N.M.E.	N.M.E.	
ALCOHOL USE								N.M.E.
CURRENT/FORMER	126	7 (5.6)	N.M.E.	117	1 (0.9)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	32	3 (9.4)	N.M.E.	28	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	6 (7.5)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
>= 2	78	4 (5.1)	N.M.E.	76	0	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9995
< 1 YEAR	128	10 (7.8)	N.A.	115	1 (0.9)	N.A.	7.468 (0.938, 59.442) 0.0264	
1 - < 3 YEARS	25	0	N.E.	21	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 440 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9997
YES	38	0	N.E.	37	0	N.E.	N.E. N.E.	
NO	120	10 (8.3)	N.A.	108	1 (0.9)	N.A.	7.586 (0.954, 60.314) 0.0247	
PRIOR RADIOTHERAPY								0.9995
YES	26	0	N.E.	27	0	N.E.	N.E. N.E.	
NO	132	10 (7.6)	N.A.	118	1 (0.8)	N.A.	7.411 (0.932, 58.923) 0.0269	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 441 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	2 (3.8)	N.M.E.	54	0	N.M.E.	N.M.E.	
>= 10	92	6 (6.5)	N.M.E.	89	1 (1.1)	N.M.E.	N.M.E.	
PD-L1 CPS II								N.M.E.
< 5	29	2 (6.9)	N.M.E.	24	0	N.M.E.	N.M.E.	
>= 5	116	6 (5.2)	N.M.E.	119	1 (0.8)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 442 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Hepatobiliary Disorders. PT: Hepatic Function Abnormal

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	2 (3.6)	N.M.E.	57	0	N.M.E.	N.M.E.	
>= 10%	103	8 (7.8)	N.M.E.	88	1 (1.1)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								N.M.E.
< 5%	38	2 (5.3)	N.M.E.	41	0	N.M.E.	N.M.E.	
>= 5%	120	8 (6.7)	N.M.E.	104	1 (1.0)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 443 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	17 (10.8)	N.A.	145	29 (20.0)	N.A.	0.499 (0.274, 0.911) 0.0210	
AGE								0.9387
< 65	95	11 (11.6)	N.A.	75	18 (24.0)	N.A.	0.466 (0.220, 0.986) 0.0409	
>= 65 AND < 75	55	6 (10.9)	N.A.	58	10 (17.2)	N.A.	0.554 (0.199, 1.545) 0.2529	
>= 75	8	0	N.E.	12	1 (8.3)	N.A.	N.E. 0.4142	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 444 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2140
MALE	131	12 (9.2)	N.A.	122	25 (20.5)	N.A.	0.404 (0.202, 0.807) 0.0080	
FEMALE	27	5 (18.5)	N.A.	23	4 (17.4)	N.A.	1.088 (0.292, 4.052) 0.8993	
RACE								0.1901
ASIAN	117	12 (10.3)	N.A.	104	24 (23.1)	N.A.	0.394 (0.197, 0.790) 0.0066	
NON-ASIAN	41	5 (12.2)	N.A.	41	5 (12.2)	N.A.	1.072 (0.310, 3.706) 0.9131	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 445 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4393
J/K/T	91	9 (9.9)	N.A.	85	19 (22.4)	N.A.	0.399 (0.180, 0.885) 0.0194	
REST OF ASIA	25	3 (12.0)	N.A.	19	5 (26.3)	N.A. (1.87, N.A.)	0.374 (0.089, 1.571) 0.1582	
REST OF WORLD	42	5 (11.9)	N.A.	41	5 (12.2)	N.A.	1.037 (0.300, 3.587) 0.9540	
REGION								0.2121
ASIA	116	12 (10.3)	N.A.	104	24 (23.1)	N.A.	0.399 (0.199, 0.799) 0.0073	
NON-ASIA	42	5 (11.9)	N.A.	41	5 (12.2)	N.A.	1.037 (0.300, 3.587) 0.9540	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 446 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.1378
0	71	6 (8.5)	N.A.	69	16 (23.2)	N.A.	0.318 (0.124, 0.813) 0.0117	
1	87	11 (12.6)	N.A.	74	12 (16.2)	N.A.	0.770 (0.337, 1.759) 0.5353	
WEIGHT								0.5144
< 60 KG	96	13 (13.5)	N.A.	76	17 (22.4)	N.A.	0.545 (0.264, 1.125) 0.0960	
>= 60 KG	62	4 (6.5)	N.A.	69	12 (17.4)	N.A.	0.361 (0.116, 1.119) 0.0654	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 447 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8056
STAGE I	5	0	N.E.	5	1 (20.0)	N.A. (7.92, N.A.)	N.E. 0.3173	
STAGE II	5	1 (20.0)	N.A. (1.71, N.A.)	5	0	N.E.	N.E. 0.4386	
STAGE III	33	2 (6.1)	N.A.	46	10 (21.7)	N.A.	0.262 (0.057, 1.198) 0.0633	
STAGE IV	114	14 (12.3)	N.A.	89	18 (20.2)	N.A.	0.576 (0.286, 1.160) 0.1186	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 448 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2412
GX	11	2 (18.2)	N.A. (1.48, N.A.)	14	1 (7.1)	N.A.	3.278 (0.295, 36.363) 0.3059	
G1	8	1 (12.5)	N.A. (3.09, N.A.)	8	1 (12.5)	N.A. (4.63, N.A.)	1.069 (0.067, 17.119) 0.9624	
G2	58	6 (10.3)	N.A.	50	14 (28.0)	N.A. (7.92, N.A.)	0.294 (0.111, 0.776) 0.0088	
G3	28	2 (7.1)	N.A.	36	9 (25.0)	N.A.	0.275 (0.059, 1.271) 0.0765	
NOT OTHERWISE SPECIFIED	51	6 (11.8)	N.A.	37	4 (10.8)	N.A.	1.124 (0.317, 3.987) 0.8559	

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(1) KME of median time to first AE.
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Protocol: CA209648 Page 449 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.3176
UPPER THORACIC	37	1 (2.7)	N.A.	25	6 (24.0)	N.A. (5.88, N.A.)	0.103 (0.012, 0.854) 0.0096	
MIDDLE THORACIC	50	7 (14.0)	N.A.	52	11 (21.2)	N.A.	0.669 (0.259, 1.726) 0.4025	
LOWER THORACIC	59	9 (15.3)	N.A.	60	10 (16.7)	N.A.	0.851 (0.342, 2.117) 0.7270	
GASTROESOPHAGEAL JUNCTION	11	0	N.E.	8	2 (25.0)	N.A. (0.03, N.A.)	N.E. 0.0817	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 450 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.6097
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	2 (15.4)	N.A. (4.37, N.A.)	N.E. 0.2125	
RECURRENT - DISTANT	25	2 (8.0)	N.A.	27	7 (25.9)	N.A. (7.92, N.A.)	0.255 (0.052, 1.242) 0.0692	
DE NOVO METASTATIC	107	14 (13.1)	N.A.	81	15 (18.5)	N.A.	0.677 (0.325, 1.407) 0.2928	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.A.	24	5 (20.8)	N.A.	0.244 (0.028, 2.088) 0.1623	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 451 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.5288
CURRENT/FORMER	136	15 (11.0)	N.A.	111	20 (18.0)	N.A.	0.563 (0.287, 1.104) 0.0900	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	9 (26.5)	N.A. (5.88, N.A.)	0.337 (0.073, 1.563) 0.1447	
ALCOHOL USE								0.0356*
CURRENT/FORMER	126	11 (8.7)	N.A.	117	26 (22.2)	N.A.	0.349 (0.172, 0.708) 0.0023	
NEVER/UNKNOWN	32	6 (18.8)	N.A.	28	3 (10.7)	N.A.	1.983 (0.496, 7.934) 0.3226	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 452 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.8295
<= 1	80	6 (7.5)	N.A.	69	11 (15.9)	N.A.	0.464 (0.172, 1.257) 0.1212	
>= 2	78	11 (14.1)	N.A.	76	18 (23.7)	N.A.	0.519 (0.243, 1.109) 0.0857	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2990
< 1 YEAR	128	15 (11.7)	N.A.	115	21 (18.3)	N.A.	0.610 (0.313, 1.186) 0.1410	
1 - < 3 YEARS	25	2 (8.0)	N.A.	21	6 (28.6)	7.92 (4.37, N.A.)	0.215 (0.043, 1.082) 0.0410	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 453 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.1405
YES	38	2 (5.3)	N.A. (7.92, N.A.)	37	9 (24.3)	N.A. (7.92, N.A.)	0.180 (0.039, 0.835) 0.0138	
NO	120	15 (12.5)	N.A.	108	20 (18.5)	N.A.	0.648 (0.331, 1.268) 0.2016	
PRIOR RADIOTHERAPY								0.5388
YES	26	2 (7.7)	N.A. (5.62, N.A.)	27	6 (22.2)	N.A. (5.62, N.A.)	0.322 (0.065, 1.598) 0.1439	
NO	132	15 (11.4)	N.A.	118	23 (19.5)	N.A.	0.541 (0.281, 1.039) 0.0611	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 454 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.0825
< 10	53	6 (11.3)	N.A. (5.88, N.A.)	54	17 (31.5)	N.A. (5.88, N.A.)	0.310 (0.122, 0.787) 0.0092	
>= 10	92	11 (12.0)	N.A.	89	12 (13.5)	N.A.	0.861 (0.378, 1.959) 0.7217	
PD-L1 CPS II								0.4126
< 5	29	5 (17.2)	N.A. (4.63, N.A.)	24	5 (20.8)	N.A. (4.63, N.A.)	0.901 (0.260, 3.128) 0.8701	
>= 5	116	12 (10.3)	N.A.	119	24 (20.2)	N.A.	0.462 (0.231, 0.927) 0.0261	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 455 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Vascular Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.2751
< 10%	55	6 (10.9)	N.A. (5.88, N.A.)	57	15 (26.3)	N.A. (5.88, N.A.)	0.319 (0.121, 0.842) 0.0154	
>= 10%	103	11 (10.7)	N.A.	88	14 (15.9)	N.A.	0.684 (0.310, 1.507) 0.3448	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.1887
< 5%	38	3 (7.9)	N.A. (5.88, N.A.)	41	11 (26.8)	N.A. (5.88, N.A.)	0.254 (0.071, 0.912) 0.0232	
>= 5%	120	14 (11.7)	N.A.	104	18 (17.3)	N.A.	0.650 (0.322, 1.310) 0.2251	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 456 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	12 (7.6)	N.A.	145	30 (20.7)	N.A.	0.319 (0.162, 0.627) 0.0005	
AGE								0.9517
< 65	95	8 (8.4)	N.A. (10.55, N.A.)	75	17 (22.7)	N.A. (10.55, N.A.)	0.353 (0.152, 0.821) 0.0114	
>= 65 AND < 75	55	3 (5.5)	N.A. (10.84, N.A.)	58	10 (17.2)	N.A.	0.142 (0.028, 0.725) 0.0081	
>= 75	8	1 (12.5)	N.A. (3.58, N.A.)	12	3 (25.0)	N.A. (1.91, N.A.)	0.368 (0.038, 3.576) 0.3699	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 457 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4483
MALE	131	11 (8.4)	N.A. (10.55, N.A.)	122	25 (20.5)	N.A. (10.55, N.A.)	0.348 (0.169, 0.715) 0.0027	
FEMALE	27	1 (3.7)	N.A.	23	5 (21.7)	N.A.	0.161 (0.019, 1.376) 0.0561	
RACE								0.7363
ASIAN	117	8 (6.8)	N.A. (10.55, N.A.)	104	21 (20.2)	N.A. (10.55, N.A.)	0.297 (0.131, 0.675) 0.0021	
NON-ASIAN	41	4 (9.8)	N.A.	41	9 (22.0)	N.A.	0.376 (0.113, 1.249) 0.0978	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 458 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.7103
J/K/T	91	5 (5.5)	N.A.	85	17 (20.0)	N.A. (10.55, N.A.)	0.257 (0.094, 0.700) 0.0043	
REST OF ASIA	25	2 (8.0)	N.A.	19	4 (21.1)	N.A. (3.42, N.A.)	0.311 (0.057, 1.712) 0.1563	
REST OF WORLD	42	5 (11.9)	N.A.	41	9 (22.0)	N.A.	0.413 (0.133, 1.279) 0.1149	
REGION								0.4280
ASIA	116	7 (6.0)	N.A.	104	21 (20.2)	N.A. (10.55, N.A.)	0.272 (0.115, 0.642) 0.0015	
NON-ASIA	42	5 (11.9)	N.A.	41	9 (22.0)	N.A.	0.413 (0.133, 1.279) 0.1149	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 459 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.0851
0	71	3 (4.2)	N.A. (10.55, N.A.)	69	16 (23.2)	N.A. (10.55, N.A.)	0.135 (0.039, 0.470) 0.0003	
1	87	9 (10.3)	N.A.	74	13 (17.6)	N.A.	0.568 (0.241, 1.339) 0.1916	
WEIGHT								0.4031
< 60 KG	96	5 (5.2)	N.A. (10.55, N.A.)	76	15 (19.7)	N.A. (10.55, N.A.)	0.240 (0.087, 0.664) 0.0029	
>= 60 KG	62	7 (11.3)	N.A.	69	15 (21.7)	N.A.	0.439 (0.176, 1.097) 0.0706	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 460 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9430
STAGE I	5	0	N.E.	5	1 (20.0)	N.A. (0.89, N.A.)	N.E. 0.3173	
STAGE II	5	0	N.E.	5	0	N.E.	N.E. N.E.	
STAGE III	33	1 (3.0)	N.A.	46	7 (15.2)	N.A. (10.55, N.A.)	0.157 (0.019, 1.325) 0.0545	
STAGE IV	114	11 (9.6)	N.A.	89	22 (24.7)	N.A.	0.353 (0.170, 0.735) 0.0037	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 461 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.7506
GX	11	1 (9.1)	N.A. (4.76, N.A.)	14	1 (7.1)	N.A.	2.208 (0.138, 35.300) 0.5654	
G1	8	0	N.E.	8	1 (12.5)	N.A. (4.53, N.A.)	N.E. 0.3173	
G2	58	6 (10.3)	N.A.	50	12 (24.0)	N.A. (10.55, N.A.)	0.387 (0.145, 1.034) 0.0496	
G3	28	3 (10.7)	N.A. (10.84, N.A.)	36	11 (30.6)	N.A. (4.44, N.A.)	0.262 (0.071, 0.960) 0.0310	
NOT OTHERWISE SPECIFIED	51	1 (2.0)	N.A.	37	5 (13.5)	N.A. (6.97, N.A.)	0.117 (0.013, 1.012) 0.0200	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
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Protocol: CA209648 Page 462 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7553
UPPER THORACIC	37	2 (5.4)	N.A.	25	3 (12.0)	N.A.	0.424 (0.071, 2.547) 0.3326	
MIDDLE THORACIC	50	6 (12.0)	N.A. (10.55, N.A.)	52	14 (26.9)	N.A.	0.444 (0.170, 1.156) 0.0875	
LOWER THORACIC	59	3 (5.1)	N.A.	60	13 (21.7)	N.A.	0.186 (0.051, 0.678) 0.0048	
GASTROESOPHAGEAL JUNCTION	11	1 (9.1)	N.A. (10.18, N.A.)	8	0	N.E.	N.E. N.A.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 463 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.5620
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	3 (23.1)	N.A. (0.89, N.A.)	N.E. 0.1436	
RECURRENT - DISTANT	25	1 (4.0)	N.A.	27	3 (11.1)	N.A.	0.358 (0.037, 3.447) 0.3535	
DE NOVO METASTATIC	107	9 (8.4)	N.A.	81	22 (27.2)	N.A.	0.282 (0.129, 0.618) 0.0008	
UNRESECTABLE ADVANCED	18	2 (11.1)	N.A. (10.18, N.A.)	24	2 (8.3)	N.A. (10.55, N.A.)	0.964 (0.131, 7.082) 0.9712	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 464 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.8715
CURRENT/FORMER	136	10 (7.4)	N.A.	111	21 (18.9)	N.A. (10.55, N.A.)	0.327 (0.152, 0.704) 0.0028	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	9 (26.5)	N.A.	0.328 (0.071, 1.521) 0.1331	
ALCOHOL USE								0.3554
CURRENT/FORMER	126	11 (8.7)	N.A.	117	24 (20.5)	N.A. (10.55, N.A.)	0.366 (0.177, 0.754) 0.0046	
NEVER/UNKNOWN	32	1 (3.1)	N.A.	28	6 (21.4)	N.A. (6.97, N.A.)	0.141 (0.017, 1.171) 0.0342	

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(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 465 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.4096
<= 1	80	5 (6.3)	N.A. (10.55, N.A.)	69	16 (23.2)	N.A. (10.55, N.A.)	0.233 (0.085, 0.641) 0.0022	
>= 2	78	7 (9.0)	N.A.	76	14 (18.4)	N.A.	0.435 (0.173, 1.094) 0.0694	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9886
< 1 YEAR	128	11 (8.6)	N.A. (10.55, N.A.)	115	24 (20.9)	N.A. (10.55, N.A.)	0.355 (0.171, 0.734) 0.0037	
1 - < 3 YEARS	25	0	N.E.	21	5 (23.8)	N.A. (2.46, N.A.)	N.E. 0.0084	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 466 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4732
YES	38	1 (2.6)	N.A.	37	5 (13.5)	N.A.	0.148 (0.017, 1.295) 0.0478	
NO	120	11 (9.2)	N.A. (10.55, N.A.)	108	25 (23.1)	N.A. (10.55, N.A.)	0.361 (0.176, 0.742) 0.0039	
PRIOR RADIOTHERAPY								0.6210
YES	26	1 (3.8)	N.A.	27	5 (18.5)	N.A.	0.200 (0.023, 1.715) 0.1029	
NO	132	11 (8.3)	N.A. (10.55, N.A.)	118	25 (21.2)	N.A. (10.55, N.A.)	0.332 (0.161, 0.684) 0.0017	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 467 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.4544
< 10	53	5 (9.4)	N.A.	54	15 (27.8)	10.55 (10.55, N.A.)	0.285 (0.102, 0.796) 0.0108	
>= 10	92	7 (7.6)	N.A.	89	13 (14.6)	N.A.	0.471 (0.186, 1.197) 0.1060	
PD-L1 CPS II								0.9767
< 5	29	3 (10.3)	N.A.	24	6 (25.0)	N.A.	0.397 (0.099, 1.588) 0.1755	
>= 5	116	9 (7.8)	N.A.	119	22 (18.5)	N.A.	0.359 (0.164, 0.789) 0.0079	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
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Protocol: CA209648 Page 468 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Renal and Urinary Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.7417
< 10%	55	4 (7.3)	N.A.	57	12 (21.1)	N.A.	0.269 (0.084, 0.863) 0.0186	
>= 10%	103	8 (7.8)	N.A.	88	18 (20.5)	N.A. (10.55, N.A.)	0.353 (0.153, 0.816) 0.0111	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.4876
< 5%	38	2 (5.3)	N.A. (10.84, N.A.)	41	9 (22.0)	N.A. (6.97, N.A.)	0.171 (0.034, 0.852) 0.0168	
>= 5%	120	10 (8.3)	N.A.	104	21 (20.2)	N.A.	0.378 (0.177, 0.807) 0.0090	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 469 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	2 (1.3)	N.A.	145	11 (7.6)	N.A.	0.149 (0.033, 0.673) 0.0043	
AGE								N.M.E.
< 65	95	2 (2.1)	N.M.E.	75	7 (9.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	0	N.M.E.	58	4 (6.9)	N.M.E.	N.M.E.	
>= 75	8	0	N.M.E.	12	0	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
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Protocol: CA209648 Page 470 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9913
MALE	131	2 (1.5)	N.A.	122	8 (6.6)	N.A.	0.196 (0.041, 0.930) 0.0229	
FEMALE	27	0	N.E.	23	3 (13.0)	N.A.	N.E. 0.0573	
RACE								N.M.E.
ASIAN	117	1 (0.9)	N.M.E.	104	6 (5.8)	N.M.E.	N.M.E.	
NON-ASIAN	41	1 (2.4)	N.M.E.	41	5 (12.2)	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
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(3) Unstratified log-rank test.
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Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	1 (1.1)	N.M.E.	85	6 (7.1)	N.M.E.	N.M.E.	
REST OF ASIA	25	0	N.M.E.	19	0	N.M.E.	N.M.E.	
REST OF WORLD	42	1 (2.4)	N.M.E.	41	5 (12.2)	N.M.E.	N.M.E.	
REGION								N.M.E.
ASIA	116	1 (0.9)	N.M.E.	104	6 (5.8)	N.M.E.	N.M.E.	
NON-ASIA	42	1 (2.4)	N.M.E.	41	5 (12.2)	N.M.E.	N.M.E.	

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Protocol: CA209648 Page 472 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	2 (2.8)	N.M.E.	69	6 (8.7)	N.M.E.	N.M.E.	
1	87	0	N.M.E.	74	5 (6.8)	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	0	N.M.E.	76	4 (5.3)	N.M.E.	N.M.E.	
>= 60 KG	62	2 (3.2)	N.M.E.	69	7 (10.1)	N.M.E.	N.M.E.	

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Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	1 (20.0)	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	
STAGE II	5	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	
STAGE III	33	1 (3.0)	N.M.E.	46	2 (4.3)	N.M.E.	N.M.E.	
STAGE IV	114	0	N.M.E.	89	7 (7.9)	N.M.E.	N.M.E.	

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(3) Unstratified log-rank test.
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Protocol: CA209648 Page 474 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
G2	58	2 (3.4)	N.M.E.	50	4 (8.0)	N.M.E.	N.M.E.	
G3	28	0	N.M.E.	36	4 (11.1)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	0	N.M.E.	37	2 (5.4)	N.M.E.	N.M.E.	

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Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	0	N.M.E.	25	3 (12.0)	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	1 (2.0)	N.M.E.	52	5 (9.6)	N.M.E.	N.M.E.	
LOWER THORACIC	59	1 (1.7)	N.M.E.	60	3 (5.0)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	0	N.M.E.	8	0	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 476 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	0	N.M.E.	13	1 (7.7)	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	2 (8.0)	N.M.E.	27	1 (3.7)	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	0	N.M.E.	81	6 (7.4)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	0	N.M.E.	24	3 (12.5)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								N.M.E.
CURRENT/FORMER	136	2 (1.5)	N.M.E.	111	7 (6.3)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	22	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	
ALCOHOL USE								N.M.E.
CURRENT/FORMER	126	2 (1.6)	N.M.E.	117	6 (5.1)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	32	0	N.M.E.	28	5 (17.9)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 478 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	2 (2.5)	N.M.E.	69	6 (8.7)	N.M.E.	N.M.E.	
>= 2	78	0	N.M.E.	76	5 (6.6)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9996
< 1 YEAR	128	2 (1.6)	N.A.	115	10 (8.7)	N.A.	0.155 (0.034, 0.714) 0.0061	
1 - < 3 YEARS	25	0	N.E.	21	0	N.E.	N.E. N.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 479 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								N.M.E.
YES	38	2 (5.3)	N.M.E.	37	3 (8.1)	N.M.E.	N.M.E.	
NO	120	0	N.M.E.	108	8 (7.4)	N.M.E.	N.M.E.	
PRIOR RADIOTHERAPY								0.9944
YES	26	0	N.E.	27	2 (7.4)	N.A.	N.E. 0.1657	
NO	132	2 (1.5)	N.A.	118	9 (7.6)	N.A.	0.171 (0.037, 0.798) 0.0110	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 480 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9925
< 10	53	0	N.E.	54	2 (3.7)	N.A.	N.E. 0.1611	
>= 10	92	2 (2.2)	N.A.	89	8 (9.0)	N.A.	0.216 (0.046, 1.020) 0.0334	
PD-L1 CPS II								0.9996
< 5	29	0	N.E.	24	0	N.E.	N.E. N.E.	
>= 5	116	2 (1.7)	N.A.	119	10 (8.4)	N.A.	0.181 (0.040, 0.831) 0.0135	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

Protocol: CA209648 Page 481 of 481

Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Ear and Labyrinth Disorders

Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3399
< 10%	55	1 (1.8)	N.A.	57	2 (3.5)	N.A.	0.428 (0.038, 4.777) 0.4778	
>= 10%	103	1 (1.0)	N.A.	88	9 (10.2)	N.A.	0.090 (0.011, 0.711) 0.0040	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.3002
< 5%	38	1 (2.6)	N.A.	41	2 (4.9)	N.A.	0.482 (0.043, 5.333) 0.5426	
>= 5%	120	1 (0.8)	N.A.	104	9 (8.7)	N.A.	0.087 (0.011, 0.689) 0.0035	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:41:50

4.2.6 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren UE (CTCAE Grad ≥ 3) auf SOC/PT-Ebene

Protocol: CA209648 Page 1 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	26 (16.5)	N.A. (24.18, N.A.)	145	38 (26.2)	N.A.	0.506 (0.301, 0.851) 0.0089	
AGE								0.9798
< 65	95	16 (16.8)	N.A. (24.18, N.A.)	75	21 (28.0)	N.A.	0.505 (0.258, 0.989) 0.0425	
>= 65 AND < 75	55	7 (12.7)	N.A.	58	13 (22.4)	N.A. (7.85, N.A.)	0.514 (0.204, 1.298) 0.1517	
>= 75	8	3 (37.5)	22.44 (1.15, N.A.)	12	4 (33.3)	N.A. (0.53, N.A.)	0.607 (0.110, 3.339) 0.5622	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 2 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1789
MALE	131	23 (17.6)	N.A. (22.44, N.A.)	122	37 (30.3)	N.A. (7.43, N.A.)	0.454 (0.263, 0.783) 0.0036	
FEMALE	27	3 (11.1)	N.A.	23	1 (4.3)	N.A.	2.523 (0.262, 24.259) 0.4063	
RACE								0.9325
ASIAN	117	19 (16.2)	N.A. (24.18, N.A.)	104	27 (26.0)	N.A.	0.526 (0.287, 0.967) 0.0353	
NON-ASIAN	41	7 (17.1)	N.A. (12.94, N.A.)	41	11 (26.8)	N.A. (6.44, N.A.)	0.453 (0.164, 1.246) 0.1175	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 3 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.9608
J/K/T	91	14 (15.4)	N.A. (24.18, N.A.)	85	22 (25.9)	N.A. (7.85, N.A.)	0.487 (0.241, 0.987) 0.0414	
REST OF ASIA	25	5 (20.0)	N.A. (6.47, N.A.)	19	5 (26.3)	N.A. (2.27, N.A.)	0.627 (0.181, 2.174) 0.4580	
REST OF WORLD	42	7 (16.7)	N.A. (17.64, N.A.)	41	11 (26.8)	N.A. (6.44, N.A.)	0.440 (0.160, 1.209) 0.1036	
REGION								0.8761
ASIA	116	19 (16.4)	N.A. (24.18, N.A.)	104	27 (26.0)	N.A.	0.533 (0.290, 0.980) 0.0392	
NON-ASIA	42	7 (16.7)	N.A. (17.64, N.A.)	41	11 (26.8)	N.A. (6.44, N.A.)	0.440 (0.160, 1.209) 0.1036	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 4 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.1174
0	71	10 (14.1)	N.A. (22.44, N.A.)	69	22 (31.9)	N.A. (6.44, N.A.)	0.331 (0.152, 0.721) 0.0034	
1	87	16 (18.4)	N.A. (24.18, N.A.)	74	15 (20.3)	N.A.	0.772 (0.370, 1.611) 0.4888	
WEIGHT								0.8403
< 60 KG	96	15 (15.6)	N.A. (22.44, N.A.)	76	21 (27.6)	N.A.	0.511 (0.259, 1.005) 0.0470	
>= 60 KG	62	11 (17.7)	N.A. (17.64, N.A.)	69	17 (24.6)	N.A. (7.85, N.A.)	0.499 (0.221, 1.123) 0.0879	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 5 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9913
STAGE I	5	0	N.E.	5	1 (20.0)	N.A. (2.76, N.A.)	N.E. 0.3173	
STAGE II	5	1 (20.0)	N.A. (3.81, N.A.)	5	0	N.E.	N.E. 0.4386	
STAGE III	33	5 (15.2)	N.A. (12.94, N.A.)	46	12 (26.1)	N.A. (7.43, N.A.)	0.471 (0.163, 1.362) 0.1550	
STAGE IV	114	20 (17.5)	N.A. (22.44, N.A.)	89	25 (28.1)	N.A. (7.85, N.A.)	0.515 (0.279, 0.952) 0.0311	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 6 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.8323
GX	11	1 (9.1)	N.A. (6.37, N.A.)	14	3 (21.4)	N.A. (5.19, N.A.)	0.538 (0.053, 5.493) 0.5963	
G1	8	1 (12.5)	N.A. (3.81, N.A.)	8	2 (25.0)	N.A. (1.64, N.A.)	0.587 (0.053, 6.506) 0.6605	
G2	58	9 (15.5)	24.18 (22.44, N.A.)	50	16 (32.0)	N.A. (6.37, N.A.)	0.331 (0.136, 0.809) 0.0109	
G3	28	4 (14.3)	N.A. (17.64, N.A.)	36	9 (25.0)	N.A.	0.409 (0.111, 1.513) 0.1671	
NOT OTHERWISE SPECIFIED	51	10 (19.6)	N.A.	37	8 (21.6)	N.A. (7.43, N.A.)	0.815 (0.320, 2.077) 0.6640	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 7 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.5170
UPPER THORACIC	37	6 (16.2)	N.A.	25	3 (12.0)	N.A.	1.203	
						(6.44, N.A.)	(0.299, 4.842)	
							0.7949	
MIDDLE THORACIC	50	7 (14.0)	N.A.	52	16 (30.8)	N.A.	0.330	
			(22.44, N.A.)			(6.37, N.A.)	(0.121, 0.902)	
							0.0230	
LOWER THORACIC	59	9 (15.3)	N.A.	60	19 (31.7)	N.A.	0.373	
						(6.44, N.A.)	(0.163, 0.855)	
							0.0153	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	N.A.	8	0	N.E.	N.E.	
			(1.87, N.A.)				0.2478	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 8 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9414
RECURRENT - LOCO-REGIONAL	8	1 (12.5)	N.A. (12.94, N.A.)	13	4 (30.8)	N.A. (1.61, N.A.)	0.242 (0.025, 2.364) 0.1936	
RECURRENT - DISTANT	25	3 (12.0)	N.A.	27	4 (14.8)	N.A.	0.780 (0.175, 3.488) 0.7437	
DE NOVO METASTATIC	107	19 (17.8)	N.A. (22.44, N.A.)	81	24 (29.6)	N.A. (6.44, N.A.)	0.516 (0.278, 0.959) 0.0334	
UNRESECTABLE ADVANCED	18	3 (16.7)	24.18 (6.47, N.A.)	24	6 (25.0)	N.A. (7.43, N.A.)	0.367 (0.074, 1.826) 0.2022	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 9 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.6037
CURRENT/FORMER	136	22 (16.2)	N.A. (24.18, N.A.)	111	31 (27.9)	N.A. (7.85, N.A.)	0.475 (0.269, 0.837) 0.0085	
NEVER/UNKNOWN	22	4 (18.2)	N.A. (6.47, N.A.)	34	7 (20.6)	N.A.	0.690 (0.194, 2.459) 0.5660	
ALCOHOL USE								0.2985
CURRENT/FORMER	126	20 (15.9)	N.A. (24.18, N.A.)	117	33 (28.2)	N.A. (7.85, N.A.)	0.452 (0.253, 0.807) 0.0059	
NEVER/UNKNOWN	32	6 (18.8)	N.A. (17.64, N.A.)	28	5 (17.9)	N.A.	0.831 (0.240, 2.877) 0.7738	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 10 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9273
<= 1	80	12 (15.0)	N.A. (22.44, N.A.)	69	17 (24.6)	N.A.	0.468 (0.213, 1.027) 0.0525	
>= 2	78	14 (17.9)	N.A. (24.18, N.A.)	76	21 (27.6)	N.A. (6.44, N.A.)	0.548 (0.274, 1.097) 0.0846	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9077
< 1 YEAR	128	21 (16.4)	N.A. (24.18, N.A.)	115	32 (27.8)	N.A. (7.85, N.A.)	0.465 (0.261, 0.829) 0.0078	
1 - < 3 YEARS	25	4 (16.0)	N.A. (12.94, N.A.)	21	5 (23.8)	N.A. (6.44, N.A.)	0.453 (0.108, 1.905) 0.2677	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9155
YES	38	4 (10.5)	N.A. (12.94, N.A.)	37	6 (16.2)	N.A.	0.473 (0.127, 1.759) 0.2542	
NO	120	22 (18.3)	N.A. (22.44, N.A.)	108	32 (29.6)	N.A. (7.85, N.A.)	0.514 (0.292, 0.906) 0.0189	
PRIOR RADIOTHERAPY								0.8027
YES	26	4 (15.4)	N.A.	27	7 (25.9)	N.A. (4.80, N.A.)	0.539 (0.158, 1.843) 0.3156	
NO	132	22 (16.7)	N.A. (22.44, N.A.)	118	31 (26.3)	N.A.	0.502 (0.283, 0.890) 0.0162	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 12 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9388
< 10	53	10 (18.9)	24.18 (22.44, N.A.)	54	17 (31.5)	N.A. (6.37, N.A.)	0.435 (0.187, 1.010) 0.0456	
>= 10	92	12 (13.0)	N.A.	89	20 (22.5)	N.A.	0.529 (0.257, 1.090) 0.0795	
PD-L1 CPS II								0.7192
< 5	29	6 (20.7)	24.18 (22.44, N.A.)	24	7 (29.2)	N.A. (3.19, N.A.)	0.481 (0.141, 1.644) 0.2321	
>= 5	116	16 (13.8)	N.A.	119	30 (25.2)	N.A.	0.491 (0.266, 0.904) 0.0198	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 13 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.8971
< 10%	55	10 (18.2)	N.A. (22.44, N.A.)	57	16 (28.1)	N.A. (7.43, N.A.)	0.446 (0.190, 1.044) 0.0554	
>= 10%	103	16 (15.5)	N.A.	88	22 (25.0)	N.A.	0.551 (0.284, 1.068) 0.0735	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.8875
< 5%	38	7 (18.4)	24.18 (22.44, N.A.)	41	11 (26.8)	N.A. (6.44, N.A.)	0.428 (0.148, 1.232) 0.1050	
>= 5%	120	19 (15.8)	N.A.	104	27 (26.0)	N.A.	0.536 (0.294, 0.977) 0.0387	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 14 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	16 (10.1)	N.A.	145	26 (17.9)	N.A.	0.494 (0.259, 0.941) 0.0286	
AGE								0.3383
< 65	95	10 (10.5)	N.A.	75	14 (18.7)	N.A.	0.529 (0.233, 1.203) 0.1228	
>= 65 AND < 75	55	3 (5.5)	N.A.	58	10 (17.2)	N.A.	0.300 (0.082, 1.094) 0.0532	
>= 75	8	3 (37.5)	22.44 (1.15, N.A.)	12	2 (16.7)	N.A. (2.53, N.A.)	1.382 (0.194, 9.858) 0.7460	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 15 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9886
MALE	131	14 (10.7)	N.A.	122	26 (21.3)	N.A.	0.430 (0.219, 0.846) 0.0118	
FEMALE	27	2 (7.4)	N.A.	23	0	N.E.	N.E. 0.1904	
RACE								0.2555
ASIAN	117	11 (9.4)	N.A.	104	21 (20.2)	N.A.	0.411 (0.193, 0.875) 0.0171	
NON-ASIAN	41	5 (12.2)	N.A. (17.64, N.A.)	41	5 (12.2)	N.A.	0.868 (0.243, 3.101) 0.8280	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 16 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4768
J/K/T	91	8 (8.8)	N.A.	85	18 (21.2)	N.A.	0.367 (0.153, 0.881) 0.0194	
REST OF ASIA	25	3 (12.0)	N.A.	19	3 (15.8)	N.A. (3.19, N.A.)	0.626 (0.126, 3.118) 0.5638	
REST OF WORLD	42	5 (11.9)	N.A. (17.64, N.A.)	41	5 (12.2)	N.A.	0.843 (0.236, 3.007) 0.7920	
REGION								0.2795
ASIA	116	11 (9.5)	N.A.	104	21 (20.2)	N.A.	0.416 (0.196, 0.885) 0.0188	
NON-ASIA	42	5 (11.9)	N.A. (17.64, N.A.)	41	5 (12.2)	N.A.	0.843 (0.236, 3.007) 0.7920	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 17 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.0649
0	71	5 (7.0)	N.A. (22.44, N.A.)	69	16 (23.2)	N.A.	0.218 (0.073, 0.654) 0.0028	
1	87	11 (12.6)	N.A.	74	10 (13.5)	N.A.	0.884 (0.367, 2.126) 0.7833	
WEIGHT								0.6291
< 60 KG	96	9 (9.4)	N.A. (22.44, N.A.)	76	15 (19.7)	N.A.	0.427 (0.181, 1.009) 0.0456	
>= 60 KG	62	7 (11.3)	N.A.	69	11 (15.9)	N.A.	0.618 (0.235, 1.623) 0.3241	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 18 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9984
STAGE I	5	0	N.E.	5	1 (20.0)	N.A. (2.76, N.A.)	N.E. 0.3173	
STAGE II	5	1 (20.0)	N.A. (3.81, N.A.)	5	0	N.E.	N.E. 0.4386	
STAGE III	33	3 (9.1)	N.A.	46	8 (17.4)	N.A.	0.492 (0.130, 1.857) 0.2853	
STAGE IV	114	12 (10.5)	N.A. (22.44, N.A.)	89	17 (19.1)	N.A.	0.478 (0.220, 1.036) 0.0560	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 19 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.7696
GX	11	1 (9.1)	N.A. (6.37, N.A.)	14	3 (21.4)	N.A. (5.19, N.A.)	0.538 (0.053, 5.493) 0.5963	
G1	8	1 (12.5)	N.A. (3.81, N.A.)	8	2 (25.0)	N.A. (1.64, N.A.)	0.587 (0.053, 6.506) 0.6605	
G2	58	4 (6.9)	N.A. (22.44, N.A.)	50	10 (20.0)	N.A.	0.247 (0.068, 0.899) 0.0215	
G3	28	4 (14.3)	N.A. (17.64, N.A.)	36	6 (16.7)	N.A.	0.672 (0.168, 2.688) 0.5718	
NOT OTHERWISE SPECIFIED	51	6 (11.8)	N.A.	37	5 (13.5)	N.A. (7.43, N.A.)	0.849 (0.258, 2.797) 0.7877	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 20 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.7550
UPPER THORACIC	37	1 (2.7)	N.A.	25	3 (12.0)	N.A.	0.200	
						(6.44, N.A.)	(0.021, 1.938)	
							0.1236	
MIDDLE THORACIC	50	4 (8.0)	N.A.	52	11 (21.2)	N.A.	0.312	
			(22.44, N.A.)			(7.43, N.A.)	(0.087, 1.120)	
							0.0590	
LOWER THORACIC	59	9 (15.3)	N.A.	60	12 (20.0)	N.A.	0.673	
							(0.278, 1.630)	
							0.3777	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.A.	8	0	N.E.	N.E.	
			(1.87, N.A.)				0.2478	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 21 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.9967
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	2 (15.4)	N.A. (2.76, N.A.)	N.E. 0.2378	
RECURRENT - DISTANT	25	2 (8.0)	N.A.	27	3 (11.1)	N.A.	0.694 (0.116, 4.154) 0.6874	
DE NOVO METASTATIC	107	12 (11.2)	N.A. (22.44, N.A.)	81	17 (21.0)	N.A.	0.462 (0.213, 1.002) 0.0452	
UNRESECTABLE ADVANCED	18	2 (11.1)	N.A. (6.47, N.A.)	24	4 (16.7)	N.A. (7.43, N.A.)	0.557 (0.101, 3.064) 0.4953	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.7099
CURRENT/FORMER	136	14 (10.3)	N.A.	111	22 (19.8)	N.A.	0.474 (0.239, 0.943) 0.0294	
NEVER/UNKNOWN	22	2 (9.1)	N.A. (17.64, N.A.)	34	4 (11.8)	N.A.	0.537 (0.088, 3.262) 0.4946	
ALCOHOL USE								0.1178
CURRENT/FORMER	126	11 (8.7)	N.A.	117	23 (19.7)	N.A.	0.392 (0.186, 0.824) 0.0104	
NEVER/UNKNOWN	32	5 (15.6)	N.A. (17.64, N.A.)	28	3 (10.7)	N.A.	1.226 (0.274, 5.486) 0.7898	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9223
<= 1	80	8 (10.0)	N.A. (22.44, N.A.)	69	12 (17.4)	N.A.	0.446 (0.171, 1.162) 0.0900	
>= 2	78	8 (10.3)	N.A.	76	14 (18.4)	N.A.	0.548 (0.229, 1.308) 0.1690	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3293
< 1 YEAR	128	13 (10.2)	N.A.	115	23 (20.0)	N.A.	0.419 (0.205, 0.856) 0.0139	
1 - < 3 YEARS	25	3 (12.0)	N.A.	21	2 (9.5)	N.A.	1.154 (0.193, 6.915) 0.8750	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 24 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2) (3)	Test for Interaction P-value (4) (5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.8097
YES	38	3 (7.9)	N.A.	37	4 (10.8)	N.A.	0.665 (0.149, 2.974) 0.5913	
NO	120	13 (10.8)	N.A.	108	22 (20.4)	N.A.	0.460 (0.224, 0.944) 0.0300	
PRIOR RADIOTHERAPY								0.8869
YES	26	2 (7.7)	N.A.	27	4 (14.8)	N.A.	0.496 (0.091, 2.708) 0.4083	
NO	132	14 (10.6)	N.A.	118	22 (18.6)	N.A.	0.485 (0.241, 0.976) 0.0383	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 25 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.8709
< 10	53	7 (13.2)	N.A. (22.44, N.A.)	54	13 (24.1)	N.A. (6.44, N.A.)	0.440 (0.167, 1.159) 0.0875	
>= 10	92	7 (7.6)	N.A.	89	12 (13.5)	N.A.	0.573 (0.225, 1.460) 0.2373	
PD-L1 CPS II								0.6522
< 5	29	5 (17.2)	N.A. (22.44, N.A.)	24	6 (25.0)	N.A.	0.579 (0.163, 2.052) 0.3911	
>= 5	116	9 (7.8)	N.A.	119	19 (16.0)	N.A.	0.471 (0.213, 1.042) 0.0570	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 26 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.8412
< 10%	55	6 (10.9)	N.A. (22.44, N.A.)	57	11 (19.3)	N.A.	0.419 (0.145, 1.208) 0.0964	
>= 10%	103	10 (9.7)	N.A.	88	15 (17.0)	N.A.	0.541 (0.236, 1.238) 0.1394	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.7766
< 5%	38	5 (13.2)	N.A. (22.44, N.A.)	41	8 (19.5)	N.A. (7.43, N.A.)	0.492 (0.148, 1.636) 0.2375	
>= 5%	120	11 (9.2)	N.A.	104	18 (17.3)	N.A.	0.487 (0.225, 1.058) 0.0632	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 27 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	4 (2.5)	N.A.	145	13 (9.0)	N.A.	0.208 (0.062, 0.694) 0.0054	
AGE								0.9238
< 65	95	1 (1.1)	N.A.	75	2 (2.7)	N.A.	0.323 (0.028, 3.681) 0.3394	
>= 65 AND < 75	55	2 (3.6)	N.A. (19.58, N.A.)	58	8 (13.8)	N.A.	0.125 (0.016, 0.999) 0.0197	
>= 75	8	1 (12.5)	N.A. (5.06, N.A.)	12	3 (25.0)	N.A. (3.84, N.A.)	0.322 (0.033, 3.183) 0.3086	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 28 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9417
MALE	131	3 (2.3)	N.A.	122	10 (8.2)	N.A.	0.251 (0.068, 0.933) 0.0264	
FEMALE	27	1 (3.7)	N.A. (19.58, N.A.)	23	3 (13.0)	N.A.	<0.001 (<0.001, N.A.) 0.0551	
RACE								0.9996
ASIAN	117	4 (3.4)	N.A.	104	13 (12.5)	N.A.	0.182 (0.051, 0.646) 0.0032	
NON-ASIAN	41	0	N.E.	41	0	N.E.	N.E. N.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 29 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								>0.9999
J/K/T	91	4 (4.4)	N.A.	85	13 (15.3)	N.A.	0.196 (0.055, 0.693) 0.0050	
REST OF ASIA	25	0	N.E.	19	0	N.E.	N.E. N.E.	
REST OF WORLD	42	0	N.E.	41	0	N.E.	N.E. N.E.	
REGION								0.9996
ASIA	116	4 (3.4)	N.A.	104	13 (12.5)	N.A.	0.184 (0.052, 0.653) 0.0034	
NON-ASIA	42	0	N.E.	41	0	N.E.	N.E. N.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 30 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9912
0	71	4 (5.6)	N.A. (19.58, N.A.)	69	11 (15.9)	N.A.	0.252 (0.077, 0.828) 0.0149	
1	87	0	N.E.	74	2 (2.7)	N.A.	N.E. 0.1404	
WEIGHT								0.8094
< 60 KG	96	3 (3.1)	N.A.	76	8 (10.5)	N.A.	0.179 (0.038, 0.854) 0.0155	
>= 60 KG	62	1 (1.6)	N.A.	69	5 (7.2)	N.A.	0.219 (0.026, 1.876) 0.1279	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 31 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients 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 INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	0	N.M.E.	5	2 (40.0)	N.M.E.	N.M.E.	
STAGE II	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE III	33	1 (3.0)	N.M.E.	46	6 (13.0)	N.M.E.	N.M.E.	
STAGE IV	114	3 (2.6)	N.M.E.	89	5 (5.6)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 32 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	3 (21.4)	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	0	N.M.E.	50	3 (6.0)	N.M.E.	N.M.E.	
G3	28	0	N.M.E.	36	3 (8.3)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	4 (7.8)	N.M.E.	37	4 (10.8)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 33 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	2 (5.4)	N.M.E.	25	3 (12.0)	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	1 (2.0)	N.M.E.	52	2 (3.8)	N.M.E.	N.M.E.	
LOWER THORACIC	59	1 (1.7)	N.M.E.	60	8 (13.3)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	0	N.M.E.	8	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 34 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	0	N.M.E.	13	3 (23.1)	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	1 (4.0)	N.M.E.	27	3 (11.1)	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	3 (2.8)	N.M.E.	81	4 (4.9)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	0	N.M.E.	24	3 (12.5)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 35 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9936
CURRENT/FORMER	136	4 (2.9)	N.A.	111	11 (9.9)	N.A.	0.213 (0.062, 0.726) 0.0073	
NEVER/UNKNOWN	22	0	N.E.	34	2 (5.9)	N.A.	N.E. 0.2691	
ALCOHOL USE								0.9995
CURRENT/FORMER	126	4 (3.2)	N.A.	117	13 (11.1)	N.A.	0.206 (0.062, 0.684) 0.0049	
NEVER/UNKNOWN	32	0	N.E.	28	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9921
<= 1	80	4 (5.0)	N.A.	69	7 (10.1)	N.A.	0.368 (0.101, 1.339) 0.1153	
>= 2	78	0	N.E.	76	6 (7.9)	N.A.	N.E. 0.0155	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.8747
< 1 YEAR	128	3 (2.3)	N.A.	115	8 (7.0)	N.A.	0.230 (0.049, 1.085) 0.0423	
1 - < 3 YEARS	25	1 (4.0)	N.A. (12.62, N.A.)	21	2 (9.5)	N.A.	0.239 (0.019, 2.996) 0.2378	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 37 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9913
YES	38	0	N.E.	37	5 (13.5)	N.A.	N.E. 0.0192	
NO	120	4 (3.3)	N.A.	108	8 (7.4)	N.A.	0.308 (0.080, 1.190) 0.0714	
PRIOR RADIOTHERAPY								0.8543
YES	26	1 (3.8)	N.A. (12.62, N.A.)	27	4 (14.8)	N.A.	0.196 (0.021, 1.802) 0.1124	
NO	132	3 (2.3)	N.A.	118	9 (7.6)	N.A.	0.204 (0.044, 0.946) 0.0242	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 38 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9136
< 10	53	1 (1.9)	N.A. (12.62, N.A.)	54	3 (5.6)	N.A.	0.216 (0.020, 2.360) 0.1788	
>= 10	92	3 (3.3)	N.A.	89	10 (11.2)	N.A.	0.226 (0.057, 0.894) 0.0219	
PD-L1 CPS II								0.9925
< 5	29	0	N.E.	24	2 (8.3)	N.A.	N.E. 0.1406	
>= 5	116	4 (3.4)	N.A.	119	11 (9.2)	N.A.	0.274 (0.081, 0.931) 0.0278	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 39 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Investigations. PT: Neutrophil Count Decreased

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.5186
< 10%	55	1 (1.8)	N.A.	57	2 (3.5)	N.A.	0.353 (0.030, 4.189) 0.3923	
>= 10%	103	3 (2.9)	N.A.	88	11 (12.5)	N.A.	0.158 (0.035, 0.713) 0.0058	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9921
< 5%	38	0	N.E.	41	2 (4.9)	N.A.	N.E. 0.1713	
>= 5%	120	4 (3.3)	N.A.	104	11 (10.6)	N.A.	0.212 (0.058, 0.777) 0.0103	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 40 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	12 (7.6)	N.A.	145	1 (0.7)	N.A.	10.670 (1.380, 82.505) 0.0047	
AGE								N.M.E.
< 65	95	7 (7.4)	N.M.E.	75	0	N.M.E.	N.M.E.	
>= 65 AND < 75	55	4 (7.3)	N.M.E.	58	1 (1.7)	N.M.E.	N.M.E.	
>= 75	8	1 (12.5)	N.M.E.	12	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 41 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9994
MALE	131	12 (9.2)	N.A.	122	1 (0.8)	N.A.	10.930 (1.412, 84.603) 0.0042	
FEMALE	27	0	N.E.	23	0	N.E.	N.E. N.E.	
RACE								0.9936
ASIAN	117	10 (8.5)	N.A.	104	1 (1.0)	N.A.	9.060 (1.158, 70.900) 0.0109	
NON-ASIAN	41	2 (4.9)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.2568	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 42 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								>0.9999
J/K/T	91	9 (9.9)	N.A.	85	1 (1.2)	N.A.	9.293 (1.176, 73.402) 0.0099	
REST OF ASIA	25	0	N.E.	19	0	N.E.	N.E. N.E.	
REST OF WORLD	42	3 (7.1)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.2063	
REGION								0.9932
ASIA	116	9 (7.8)	N.A.	104	1 (1.0)	N.A.	8.574 (1.086, 67.703) 0.0142	
NON-ASIA	42	3 (7.1)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.2063	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 43 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	9 (12.7)	N.M.E.	69	0	N.M.E.	N.M.E.	
1	87	3 (3.4)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	7 (7.3)	N.M.E.	76	0	N.M.E.	N.M.E.	
>= 60 KG	62	5 (8.1)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 44 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE II	5	1 (20.0)	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE III	33	3 (9.1)	N.M.E.	46	0	N.M.E.	N.M.E.	
STAGE IV	114	8 (7.0)	N.M.E.	89	1 (1.1)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 45 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	1 (9.1)	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	5 (8.6)	N.M.E.	50	0	N.M.E.	N.M.E.	
G3	28	2 (7.1)	N.M.E.	36	0	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	4 (7.8)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	3 (8.1)	N.M.E.	25	0	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	6 (12.0)	N.M.E.	52	0	N.M.E.	N.M.E.	
LOWER THORACIC	59	1 (1.7)	N.M.E.	60	1 (1.7)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.M.E.	8	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2) (3)	Test for Interaction P-value (4) (5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	0	N.M.E.	13	0	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	2 (8.0)	N.M.E.	27	0	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	7 (6.5)	N.M.E.	81	1 (1.2)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	3 (16.7)	N.M.E.	24	0	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 48 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9936
CURRENT/FORMER	136	12 (8.8)	N.A.	111	0	N.E.	N.E. 0.0021	
NEVER/UNKNOWN	22	0	N.E.	34	1 (2.9)	N.A.	N.E. 0.4212	
ALCOHOL USE								0.9918
CURRENT/FORMER	126	11 (8.7)	N.A.	117	0	N.E.	N.E. 0.0011	
NEVER/UNKNOWN	32	1 (3.1)	N.A. (14.55, N.A.)	28	1 (3.6)	N.A.	0.418 (0.022, 8.095) 0.5560	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9915
<= 1	80	10 (12.5)	N.A.	69	0	N.E.	N.E. 0.0037	
>= 2	78	2 (2.6)	N.A.	76	1 (1.3)	N.A.	2.127 (0.193, 23.483) 0.5282	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9931
< 1 YEAR	128	10 (7.8)	N.A.	115	1 (0.9)	N.A.	8.456 (1.072, 66.709) 0.0155	
1 - < 3 YEARS	25	1 (4.0)	N.A.	21	0	N.E.	N.E. 0.3865	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 50 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9934
YES	38	3 (7.9)	N.A.	37	0	N.E.	N.E.	
							0.1129	
NO	120	9 (7.5)	N.A.	108	1 (0.9)	N.A.	8.255	
							(1.038, 65.657)	
							0.0174	
PRIOR RADIOTHERAPY								0.9948
YES	26	1 (3.8)	N.A.	27	0	N.E.	N.E.	
							0.2864	
NO	132	11 (8.3)	N.A.	118	1 (0.8)	N.A.	9.356	
							(1.199, 73.025)	
							0.0095	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 51 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9927
< 10	53	3 (5.7)	N.A.	54	0	N.E.	N.E. 0.0689	
>= 10	92	9 (9.8)	N.A.	89	1 (1.1)	N.A.	8.345 (1.049, 66.416) 0.0168	
PD-L1 CPS II								0.9933
< 5	29	1 (3.4)	N.A.	24	0	N.E.	N.E. 0.3173	
>= 5	116	11 (9.5)	N.A.	119	1 (0.8)	N.A.	10.749 (1.381, 83.664) 0.0047	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 52 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9932
< 10%	55	2 (3.6)	N.A.	57	0	N.E.	N.E. 0.1441	
>= 10%	103	10 (9.7)	N.A.	88	1 (1.1)	N.A.	8.244 (1.048, 64.846) 0.0169	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9942
< 5%	38	1 (2.6)	N.A.	41	0	N.E.	N.E. 0.2888	
>= 5%	120	11 (9.2)	N.A.	104	1 (1.0)	N.A.	9.216 (1.182, 71.836) 0.0101	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 53 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	3 (1.9)	N.A.	145	8 (5.5)	N.A.	0.307 (0.081, 1.165) 0.0666	
AGE								N.M.E.
< 65	95	2 (2.1)	N.M.E.	75	4 (5.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	55	1 (1.8)	N.M.E.	58	3 (5.2)	N.M.E.	N.M.E.	
>= 75	8	0	N.M.E.	12	1 (8.3)	N.M.E.	N.M.E.	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 54 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	131	2 (1.5)	N.M.E.	122	7 (5.7)	N.M.E.	N.M.E.	
FEMALE	27	1 (3.7)	N.M.E.	23	1 (4.3)	N.M.E.	N.M.E.	
RACE								N.M.E.
ASIAN	117	3 (2.6)	N.M.E.	104	4 (3.8)	N.M.E.	N.M.E.	
NON-ASIAN	41	0	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Protocol: CA209648 Page 55 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	2 (2.2)	N.M.E.	85	4 (4.7)	N.M.E.	N.M.E.	
REST OF ASIA	25	1 (4.0)	N.M.E.	19	0	N.M.E.	N.M.E.	
REST OF WORLD	42	0	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	
REGION								N.M.E.
ASIA	116	3 (2.6)	N.M.E.	104	4 (3.8)	N.M.E.	N.M.E.	
NON-ASIA	42	0	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	

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(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								N.M.E.
0	71	2 (2.8)	N.M.E.	69	1 (1.4)	N.M.E.	N.M.E.	
1	87	1 (1.1)	N.M.E.	74	6 (8.1)	N.M.E.	N.M.E.	
WEIGHT								N.M.E.
< 60 KG	96	1 (1.0)	N.M.E.	76	3 (3.9)	N.M.E.	N.M.E.	
>= 60 KG	62	2 (3.2)	N.M.E.	69	5 (7.2)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 57 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	
STAGE II	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE III	33	1 (3.0)	N.M.E.	46	2 (4.3)	N.M.E.	N.M.E.	
STAGE IV	114	2 (1.8)	N.M.E.	89	5 (5.6)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
G2	58	1 (1.7)	N.M.E.	50	3 (6.0)	N.M.E.	N.M.E.	
G3	28	0	N.M.E.	36	1 (2.8)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	2 (3.9)	N.M.E.	37	3 (8.1)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	2 (5.4)	N.M.E.	25	1 (4.0)	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	0	N.M.E.	52	4 (7.7)	N.M.E.	N.M.E.	
LOWER THORACIC	59	1 (1.7)	N.M.E.	60	3 (5.0)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	0	N.M.E.	8	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	0	N.M.E.	13	1 (7.7)	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	0	N.M.E.	27	2 (7.4)	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	2 (1.9)	N.M.E.	81	5 (6.2)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.M.E.	24	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 61 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								N.M.E.
CURRENT/FORMER	136	3 (2.2)	N.M.E.	111	6 (5.4)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	22	0	N.M.E.	34	2 (5.9)	N.M.E.	N.M.E.	
ALCOHOL USE								N.M.E.
CURRENT/FORMER	126	3 (2.4)	N.M.E.	117	6 (5.1)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	32	0	N.M.E.	28	2 (7.1)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	2 (2.5)	N.M.E.	69	5 (7.2)	N.M.E.	N.M.E.	
>= 2	78	1 (1.3)	N.M.E.	76	3 (3.9)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9945
< 1 YEAR	128	3 (2.3)	N.A.	115	7 (6.1)	N.A.	0.351 (0.090, 1.367) 0.1148	
1 - < 3 YEARS	25	0	N.E.	21	1 (4.8)	N.A. (8.77, N.A.)	N.E. 0.2733	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 63 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroups	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	N	Patients with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								N.M.E.
YES	38	0	N.M.E.	37	2 (5.4)	N.M.E.	N.M.E.	
NO	120	3 (2.5)	N.M.E.	108	6 (5.6)	N.M.E.	N.M.E.	
PRIOR RADIOTHERAPY								N.M.E.
YES	26	0	N.M.E.	27	2 (7.4)	N.M.E.	N.M.E.	
NO	132	3 (2.3)	N.M.E.	118	6 (5.1)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 64 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	1 (1.9)	N.M.E.	54	2 (3.7)	N.M.E.	N.M.E.	
>= 10	92	2 (2.2)	N.M.E.	89	6 (6.7)	N.M.E.	N.M.E.	
PD-L1 CPS II								N.M.E.
< 5	29	0	N.M.E.	24	2 (8.3)	N.M.E.	N.M.E.	
>= 5	116	3 (2.6)	N.M.E.	119	6 (5.0)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:21

Protocol: CA209648 Page 65 of 65

Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	0	N.M.E.	57	4 (7.0)	N.M.E.	N.M.E.	
>= 10%	103	3 (2.9)	N.M.E.	88	4 (4.5)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								N.M.E.
< 5%	38	0	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	
>= 5%	120	3 (2.5)	N.M.E.	104	4 (3.8)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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4.2.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von SUE auf SOC/PT-Ebene

Protocol: CA209648 Page 1 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	3 (1.9)	N.A.	145	9 (6.2)	N.A.	0.267 (0.071, 1.009) 0.0376	
AGE								>0.9999
< 65	95	3 (3.2)	N.A.	75	8 (10.7)	N.A.	0.275 (0.072, 1.046) 0.0431	
>= 65 AND < 75	55	0	N.E.	58	1 (1.7)	N.A.	N.E. 0.2770	
>= 75	8	0	N.E.	12	0	N.E.	N.E. N.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 2 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	131	1 (0.8)	N.M.E.	122	5 (4.1)	N.M.E.	N.M.E.	
FEMALE	27	2 (7.4)	N.M.E.	23	4 (17.4)	N.M.E.	N.M.E.	
RACE								N.M.E.
ASIAN	117	0	N.M.E.	104	5 (4.8)	N.M.E.	N.M.E.	
NON-ASIAN	41	3 (7.3)	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 3 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								N.M.E.
J/K/T	91	0	N.M.E.	85	1 (1.2)	N.M.E.	N.M.E.	
REST OF ASIA	25	0	N.M.E.	19	4 (21.1)	N.M.E.	N.M.E.	
REST OF WORLD	42	3 (7.1)	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	
REGION								N.M.E.
ASIA	116	0	N.M.E.	104	5 (4.8)	N.M.E.	N.M.E.	
NON-ASIA	42	3 (7.1)	N.M.E.	41	4 (9.8)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 4 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9930
0	71	0	N.E.	69	1 (1.4)	N.A.	N.E. 0.2996	
1	87	3 (3.4)	N.A.	74	7 (9.5)	N.A.	0.291 (0.070, 1.211) 0.0734	
WEIGHT								N.M.E.
< 60 KG	96	3 (3.1)	N.M.E.	76	6 (7.9)	N.M.E.	N.M.E.	
>= 60 KG	62	0	N.M.E.	69	3 (4.3)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 5 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								N.M.E.
STAGE I	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	
STAGE II	5	1 (20.0)	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	
STAGE III	33	1 (3.0)	N.M.E.	46	2 (4.3)	N.M.E.	N.M.E.	
STAGE IV	114	1 (0.9)	N.M.E.	89	6 (6.7)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 6 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	0	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	2 (3.4)	N.M.E.	50	6 (12.0)	N.M.E.	N.M.E.	
G3	28	0	N.M.E.	36	2 (5.6)	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	1 (2.0)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 7 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	0	N.M.E.	25	1 (4.0)	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	0	N.M.E.	52	5 (9.6)	N.M.E.	N.M.E.	
LOWER THORACIC	59	1 (1.7)	N.M.E.	60	3 (5.0)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.M.E.	8	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 8 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								N.M.E.
RECURRENT - LOCO-REGIONAL	8	0	N.M.E.	13	2 (15.4)	N.M.E.	N.M.E.	
RECURRENT - DISTANT	25	1 (4.0)	N.M.E.	27	1 (3.7)	N.M.E.	N.M.E.	
DE NOVO METASTATIC	107	1 (0.9)	N.M.E.	81	6 (7.4)	N.M.E.	N.M.E.	
UNRESECTABLE ADVANCED	18	1 (5.6)	N.M.E.	24	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 9 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								N.M.E.
CURRENT/FORMER	136	3 (2.2)	N.M.E.	111	5 (4.5)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	22	0	N.M.E.	34	4 (11.8)	N.M.E.	N.M.E.	
ALCOHOL USE								N.M.E.
CURRENT/FORMER	126	1 (0.8)	N.M.E.	117	7 (6.0)	N.M.E.	N.M.E.	
NEVER/UNKNOWN	32	2 (6.3)	N.M.E.	28	2 (7.1)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 10 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								N.M.E.
<= 1	80	2 (2.5)	N.M.E.	69	4 (5.8)	N.M.E.	N.M.E.	
>= 2	78	1 (1.3)	N.M.E.	76	5 (6.6)	N.M.E.	N.M.E.	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								N.M.E.
< 1 YEAR	128	2 (1.6)	N.M.E.	115	6 (5.2)	N.M.E.	N.M.E.	
1 - < 3 YEARS	25	1 (4.0)	N.M.E.	21	2 (9.5)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 11 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.3720
YES	38	1 (2.6)	N.A.	37	1 (2.7)	N.A.	0.933 (0.058, 14.931) 0.9611	
NO	120	2 (1.7)	N.A.	108	8 (7.4)	N.A.	0.186 (0.038, 0.913) 0.0220	
PRIOR RADIOTHERAPY								N.M.E.
YES	26	2 (7.7)	N.M.E.	27	2 (7.4)	N.M.E.	N.M.E.	
NO	132	1 (0.8)	N.M.E.	118	7 (5.9)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 12 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI) (mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								N.M.E.
< 10	53	0	N.M.E.	54	3 (5.6)	N.M.E.	N.M.E.	
>= 10	92	3 (3.3)	N.M.E.	89	6 (6.7)	N.M.E.	N.M.E.	
PD-L1 CPS II								0.9938
< 5	29	0	N.E.	24	1 (4.2)	N.A.	N.E. 0.2877	
>= 5	116	3 (2.6)	N.A.	119	8 (6.7)	N.A.	0.334 (0.086, 1.290) 0.0960	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 13 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Gastrointestinal Disorders. PT: Vomiting

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								N.M.E.
< 10%	55	0	N.M.E.	57	4 (7.0)	N.M.E.	N.M.E.	
>= 10%	103	3 (2.9)	N.M.E.	88	5 (5.7)	N.M.E.	N.M.E.	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9996
< 5%	38	0	N.E.	41	0	N.E.	N.E.	
>= 5%	120	3 (2.5)	N.A.	104	9 (8.7)	N.A.	N.E. 0.247 (0.065, 0.941) 0.0277	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 14 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Nivo + Ipi vs. Chemotherapy Test for Interaction P-value (4)(5)
OVERALL	158	18 (11.4)	N.A.	145	1 (0.7)	N.A.	15.818 (2.101,>99.999) 0.0003	
AGE								N.M.E.
< 65	95	8 (8.4)	N.M.E.	75	0	N.M.E.	N.M.E.	
>= 65 AND < 75	55	8 (14.5)	N.M.E.	58	1 (1.7)	N.M.E.	N.M.E.	
>= 75	8	2 (25.0)	N.M.E.	12	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 15 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9992
MALE	131	18 (13.7)	N.A. (23.06, N.A.)	122	1 (0.8)	N.A.	16.266 (2.159,>99.999) 0.0003	
FEMALE	27	0	N.E.	23	0	N.E.	N.E. N.E.	
RACE								0.9932
ASIAN	117	16 (13.7)	N.A. (23.06, N.A.)	104	1 (1.0)	N.A.	14.019 (1.851,>99.999) 0.0008	
NON-ASIAN	41	2 (4.9)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.2568	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction to assess the significance of the interaction between the treatment and the subgroup.
(5) P-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
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Protocol: CA209648 Page 16 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								>0.9999
J/K/T	91	14 (15.4)	N.A. (23.06, N.A.)	85	1 (1.2)	N.A.	13.709 (1.793,>99.999) 0.0010	
REST OF ASIA	25	1 (4.0)	N.A.	19	0	N.E.	N.E. 0.4193	
REST OF WORLD	42	3 (7.1)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.2063	
REGION								0.9928
ASIA	116	15 (12.9)	N.A. (23.06, N.A.)	104	1 (1.0)	N.A.	13.560 (1.783,>99.999) 0.0010	
NON-ASIA	42	3 (7.1)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.2063	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 17 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.9899
0	71	12 (16.9)	N.A.	69	0	N.E.	N.E. 0.0004	
1	87	6 (6.9)	N.A. (23.06, N.A.)	74	1 (1.4)	N.A.	3.291 (0.365, 29.690) 0.2626	
WEIGHT								0.9930
< 60 KG	96	10 (10.4)	N.A.	76	0	N.E.	N.E. 0.0057	
>= 60 KG	62	8 (12.9)	N.A. (23.06, N.A.)	69	1 (1.4)	N.A.	8.438 (1.038, 68.624) 0.0167	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 18 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events Subgroups	Nivo + Ipi N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Patients with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	1 (20.0)	N.A. (1.97, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	1 (20.0)	N.A. (2.43, N.A.)	5	0	N.E.	N.E. 0.4386	
STAGE III	33	3 (9.1)	N.A. (14.55, N.A.)	46	0	N.E.	N.E. 0.0719	
STAGE IV	114	13 (11.4)	N.A. (23.06, N.A.)	89	1 (1.1)	N.A.	10.127 (1.314, 78.065) 0.0060	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 19 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								N.M.E.
GX	11	1 (9.1)	N.M.E.	14	0	N.M.E.	N.M.E.	
G1	8	0	N.M.E.	8	0	N.M.E.	N.M.E.	
G2	58	8 (13.8)	N.M.E.	50	0	N.M.E.	N.M.E.	
G3	28	3 (10.7)	N.M.E.	36	0	N.M.E.	N.M.E.	
NOT OTHERWISE SPECIFIED	51	6 (11.8)	N.M.E.	37	1 (2.7)	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 20 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								N.M.E.
UPPER THORACIC	37	5 (13.5)	N.M.E.	25	0	N.M.E.	N.M.E.	
MIDDLE THORACIC	50	8 (16.0)	N.M.E.	52	0	N.M.E.	N.M.E.	
LOWER THORACIC	59	2 (3.4)	N.M.E.	60	1 (1.7)	N.M.E.	N.M.E.	
GASTROESOPHAGEAL JUNCTION	11	2 (18.2)	N.M.E.	8	0	N.M.E.	N.M.E.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 21 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	0	N.E.	13	0	N.E.	N.E. N.E.	
RECURRENT - DISTANT	25	3 (12.0)	N.A.	27	0	N.E.	N.E. 0.0686	
DE NOVO METASTATIC	107	12 (11.2)	N.A. (23.06, N.A.)	81	1 (1.2)	N.A.	9.425 (1.216, 73.037) 0.0087	
UNRESECTABLE ADVANCED	18	3 (16.7)	N.A. (9.66, N.A.)	24	0	N.E.	N.E. 0.1103	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 22 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9919
CURRENT/FORMER	136	18 (13.2)	N.A. (23.06, N.A.)	111	0	N.E.	N.E. 0.0002	
NEVER/UNKNOWN	22	0	N.E.	34	1 (2.9)	N.A.	N.E. 0.4212	
ALCOHOL USE								0.9906
CURRENT/FORMER	126	16 (12.7)	N.A.	117	0	N.E.	N.E. 0.0001	
NEVER/UNKNOWN	32	2 (6.3)	N.A. (14.55, N.A.)	28	1 (3.6)	N.A.	1.203 (0.098, 14.733) 0.8850	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 23 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9905
<= 1	80	15 (18.8)	N.A. (14.55, N.A.)	69	0	N.E.	N.E. 0.0004	
>= 2	78	3 (3.8)	N.A.	76	1 (1.3)	N.A.	3.171 (0.330, 30.518) 0.2913	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9926
< 1 YEAR	128	16 (12.5)	N.A. (23.06, N.A.)	115	1 (0.9)	N.A.	13.542 (1.782,>99.999) 0.0010	
1 - < 3 YEARS	25	1 (4.0)	N.A.	21	0	N.E.	N.E. 0.3865	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 24 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9927
YES	38	4 (10.5)	N.A.	37	0	N.E.	N.E. 0.0629	
NO	120	14 (11.7)	N.A. (23.06, N.A.)	108	1 (0.9)	N.A.	12.465 (1.625, 95.625) 0.0018	
PRIOR RADIOTHERAPY								0.9917
YES	26	1 (3.8)	N.A.	27	0	N.E.	N.E. 0.2971	
NO	132	17 (12.9)	N.A. (23.06, N.A.)	118	1 (0.8)	N.A.	14.434 (1.908,>99.999) 0.0006	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 25 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9915
< 10	53	5 (9.4)	N.A.	54	0	N.E.	N.E. 0.0182	
>= 10	92	12 (13.0)	N.A. (23.06, N.A.)	89	1 (1.1)	N.A.	10.475 (1.345, 81.605) 0.0054	
PD-L1 CPS II								0.9921
< 5	29	2 (6.9)	N.A.	24	0	N.E.	N.E. 0.1649	
>= 5	116	15 (12.9)	N.A. (23.06, N.A.)	119	1 (0.8)	N.A.	14.119 (1.851,>99.999) 0.0008	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

Protocol: CA209648 Page 26 of 26

Serious Adverse Events: Subgroup Time-Adjusted Analyses
by Significant SOC/PT
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

SOC: Endocrine Disorders

Serious Adverse Events / Subgroups	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Patients with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9910
< 10%	55	6 (10.9)	N.A.	57	0	N.E.	N.E. 0.0115	
>= 10%	103	12 (11.7)	N.A. (23.06, N.A.)	88	1 (1.1)	N.A.	9.260 (1.189, 72.120) 0.0098	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9924
< 5%	38	4 (10.5)	N.A.	41	0	N.E.	N.E. 0.0337	
>= 5%	120	14 (11.7)	N.A. (23.06, N.A.)	104	1 (1.0)	N.A.	11.221 (1.462, 86.152) 0.0035	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Unstratified 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-ebr503.sas 05MAR2022:09:42:35

4.3 Zusatzanalysen Unerwünschte Ereignisse von besonderem Interesse (AESI)

4.3.1 Zusatzanalysen: Spezifische UE

4.3.1.1 Zeit bis zum ersten Auftreten von jeglichen spezifischen UE

Protocol: CA209648 Page 1 of 1

Select Adverse Events: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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	158	122 (77.2)	1.41 (0.95, 1.64)	145	79 (54.5)	5.55 (3.65, 6.44)	2.214 (1.656, 2.960)	<0.0001
SUBJECTS WITH ENDOCRINE AES	158	48 (30.4)	N.A. (9.66, N.A.)	145	2 (1.4)	N.A.	26.348 (6.389,>99.999)	<0.0001
SUBJECTS WITH GASTROINTESTINAL AES	158	51 (32.3)	11.60 (8.87, N.A.)	145	25 (17.2)	N.A. (15.28, N.A.)	1.918 (1.186, 3.103)	0.0069
SUBJECTS WITH HEPATIC AES	158	45 (28.5)	N.A.	145	13 (9.0)	N.A.	3.545 (1.908, 6.586)	<0.0001
SUBJECTS WITH PULMONARY AES	158	15 (9.5)	N.A.	145	5 (3.4)	N.A.	2.657 (0.951, 7.422)	0.0526
SUBJECTS WITH RENAL AES	158	9 (5.7)	N.A.	145	34 (23.4)	N.A. (10.55, N.A.)	0.211 (0.100, 0.443)	<0.0001
SUBJECTS WITH SKIN AES	158	75 (47.5)	5.95 (3.45, 17.05)	145	24 (16.6)	N.A.	4.011 (2.521, 6.381)	<0.0001
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	158	10 (6.3)	N.A.	145	2 (1.4)	N.A.	4.825 (1.056, 22.040)	0.0248

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahrt-ebr503.sas 08FEB2022:09:40:54

4.3.1.2 Zeit bis zum ersten Auftreten von schweren spezifischen UE (CTCAE Grad ≥ 3)

Protocol: CA209648 Page 1 of 1

Select Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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	158	40 (25.3)	N.A. (14.55, N.A.)	145	11 (7.6)	N.A.	3.407 (1.735, 6.692)	0.0002
SUBJECTS WITH ENDOCRINE AES	158	11 (7.0)	N.A.	145	0	N.E.	N.E.	0.0023
SUBJECTS WITH GASTROINTESTINAL AES	158	10 (6.3)	N.A.	145	2 (1.4)	N.A.	4.538 (0.993, 20.729)	0.0323
SUBJECTS WITH HEPATIC AES	158	16 (10.1)	N.A.	145	3 (2.1)	N.A.	4.899 (1.414, 16.971)	0.0056
SUBJECTS WITH PULMONARY AES	158	7 (4.4)	N.A.	145	2 (1.4)	N.A.	2.889 (0.581, 14.368)	0.1747
SUBJECTS WITH RENAL AES	158	2 (1.3)	N.A.	145	2 (1.4)	N.A.	1.013 (0.143, 7.192)	0.9898
SUBJECTS WITH SKIN AES	158	5 (3.2)	N.A.	145	2 (1.4)	N.A.	2.485 (0.481, 12.837)	0.2610
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	158	0	N.E.	145	0	N.E.	N.E.	N.E.

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahrt-ebr503.sas 08FEB2022:09:41:05

4.3.1.3 Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen UE

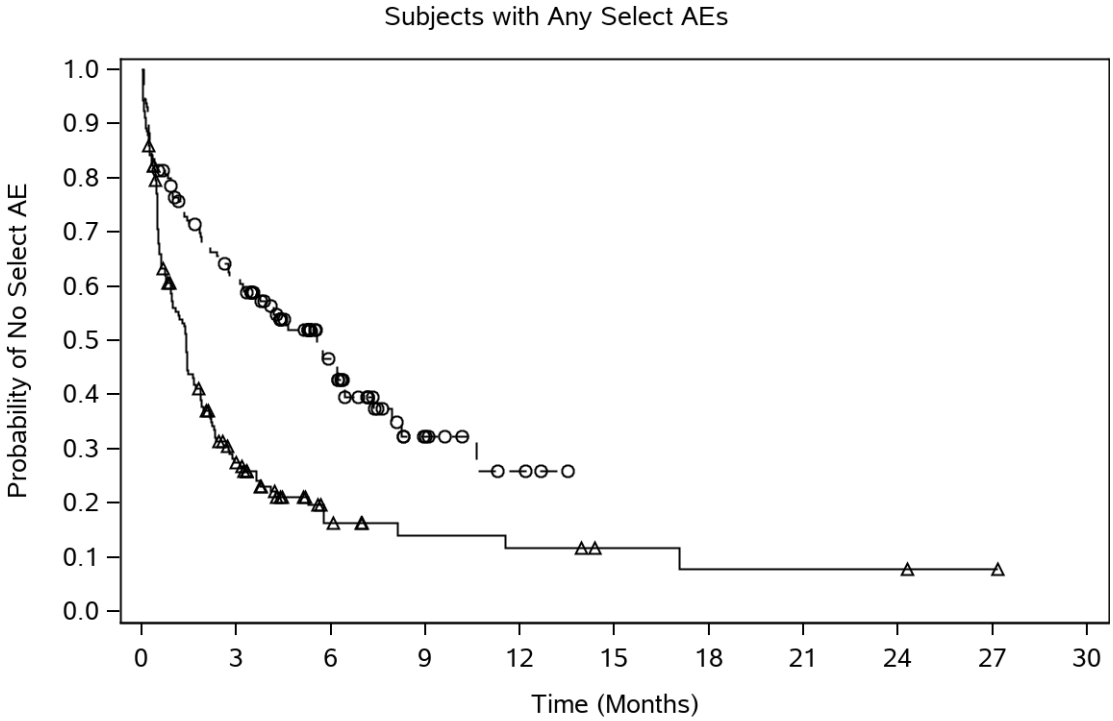
Protocol: CA209648 Page 1 of 1

Serious Select Adverse Events: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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	158	37 (23.4)	N.A. (23.06, N.A.)	145	7 (4.8)	N.A.	4.821 (2.129, 10.919)	<0.0001
SUBJECTS WITH ENDOCRINE AES	158	18 (11.4)	N.A.	145	0	N.E.	N.E.	<0.0001
SUBJECTS WITH GASTROINTESTINAL AES	158	5 (3.2)	N.A.	145	1 (0.7)	N.A.	3.672 (0.410, 32.890)	0.2127
SUBJECTS WITH HEPATIC AES	158	5 (3.2)	N.A.	145	0	N.E.	N.E.	0.0299
SUBJECTS WITH PULMONARY AES	158	9 (5.7)	N.A.	145	2 (1.4)	N.A.	3.812 (0.807, 18.002)	0.0692
SUBJECTS WITH RENAL AES	158	3 (1.9)	N.A.	145	4 (2.8)	N.A.	0.684 (0.153, 3.064)	0.6178
SUBJECTS WITH SKIN AES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.0860
SUBJECTS WITH HYPERSENSITIVITY/ INFUSION REACTION AES	158	1 (0.6)	N.A.	145	0	N.E.	N.E.	0.3101

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahrt-ebr503.sas 08FEB2022:09:41:16

4.3.1.4 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen spezifischen UE



Number of Subjects at Risk

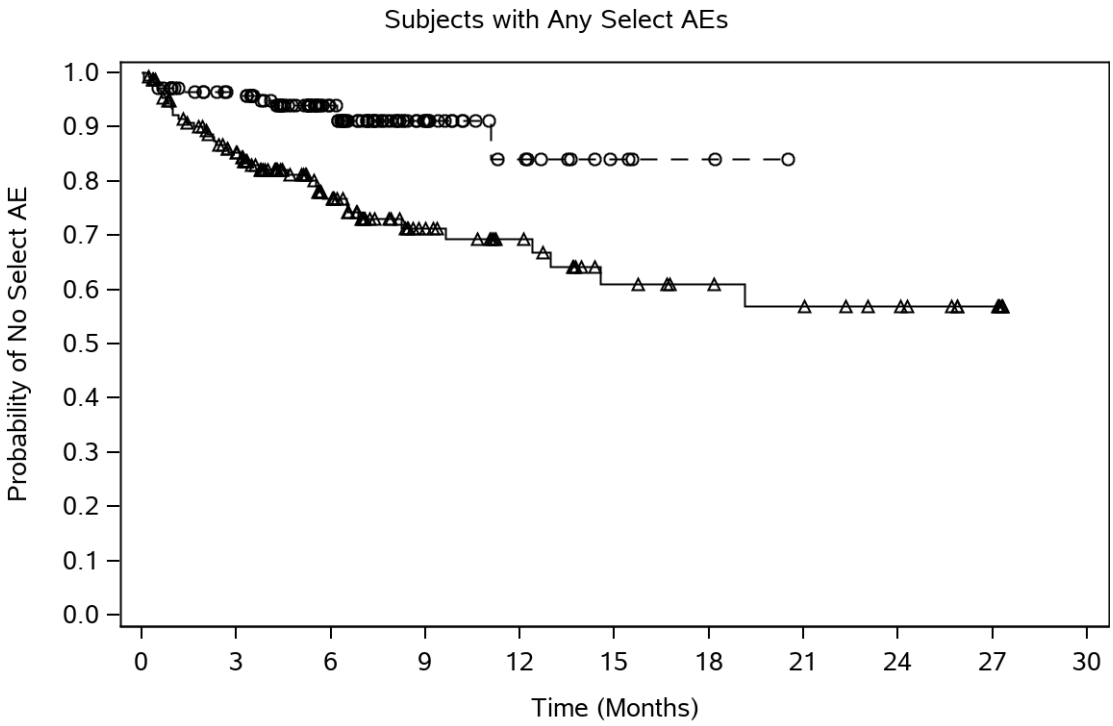
Nivo + Ipi	158	35	10	6	5	3	2	2	2	1	0
Chemo	145	83	35	9	3	0	0	0	0	0	0

Nivo + Ipi (events: 122/158), median and 95% CI: 1.41 (0.95, 1.64)

Chemo (events: 79/145), median and 95% CI: 5.55 (3.65, 6.44)

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 2.214 (1.656, 2.960), p-value: <0.0001

4.3.1.5 KM-Kurven – Zeit bis zum ersten Auftreten von schweren spezifischen UE (CTCAE Grad ≥ 3)



Number of Subjects at Risk

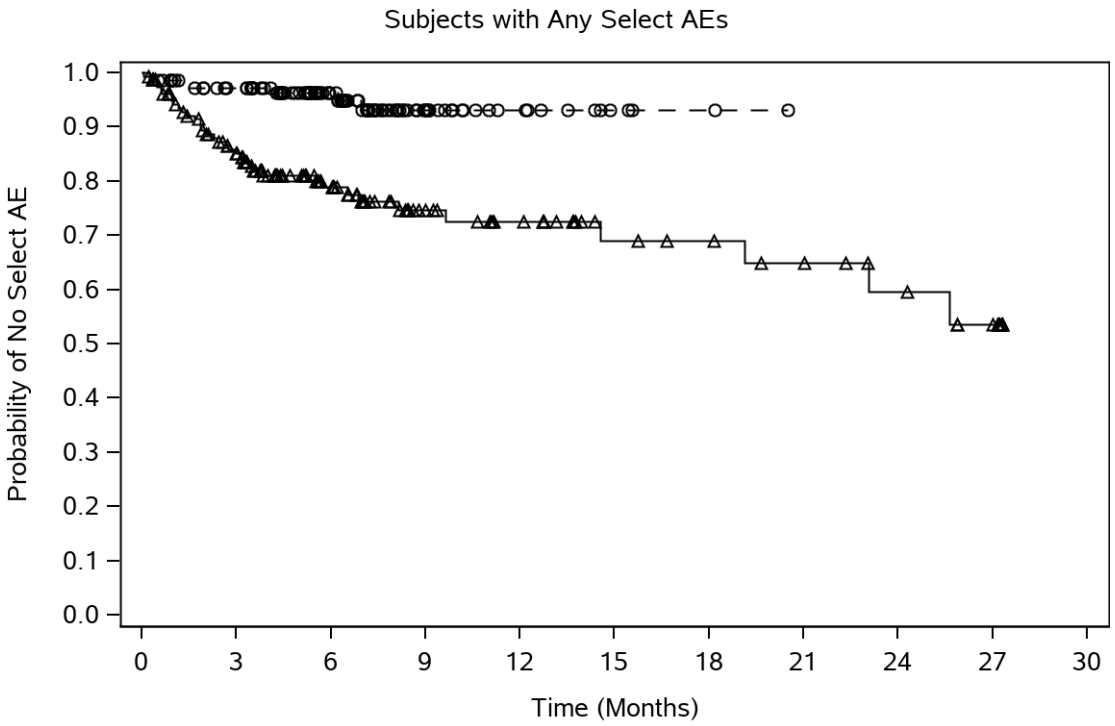
Nivo + Ipi	158	117	68	38	29	19	16	14	11	6	0
Chemo	145	127	66	26	11	4	2	0	0	0	0

Nivo + Ipi (events: 40/158), median and 95% CI: N.A. (14.55, N.A.)

Chemo (events: 11/145), median and 95% CI: N.A.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 3.407 (1.735, 6.692), p-value: 0.0002

4.3.1.6 KM-Kurven – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen UE



Number of Subjects at Risk

Nivo + Ipi	158	116	67	39	31	20	18	15	11	7	0
Chemo	145	128	66	25	11	4	2	0	0	0	0

Nivo + Ipi (events: 37/158), median and 95% CI: N.A. (23.06, N.A.)

Chemo (events: 7/145), median and 95% CI: N.A.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 4.821 (2.129, 10.919), p-value: <0.0001

4.3.1.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen spezifischen UE

Protocol: CA209648 Page 1 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	122 (77.2)	1.41 (0.95, 1.64)	145	79 (54.5)	5.55 (3.65, 6.44)	2.181 (1.633, 2.913) <0.0001	
AGE								0.7971
< 65	95	72 (75.8)	1.45 (1.18, 2.23)	75	38 (50.7)	6.41 (3.75, N.A.)	2.102 (1.408, 3.139) 0.0002	
>= 65 AND < 75	55	42 (76.4)	0.92 (0.49, 1.61)	58	33 (56.9)	4.17 (2.17, 7.95)	2.537 (1.578, 4.080) <0.0001	
>= 75	8	8 (100.0)	0.74 (0.10, 1.64)	12	8 (66.7)	6.05 (0.20, 6.44)	4.078 (1.290, 12.890) 0.0102	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 2 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5720
MALE	131	99 (75.6)	1.41 (0.95, 1.87)	122	65 (53.3)	5.75 (3.94, 7.36)	2.282 (1.657, 3.144) <0.0001	
FEMALE	27	23 (85.2)	1.41 (0.49, 2.76)	23	14 (60.9)	2.53 (1.15, N.A.)	1.649 (0.840, 3.239) 0.1444	
RACE								0.5056
ASIAN	117	91 (77.8)	1.41 (0.72, 1.71)	104	57 (54.8)	5.55 (3.65, 6.24)	2.365 (1.685, 3.320) <0.0001	
NON-ASIAN	41	31 (75.6)	1.35 (0.76, 2.76)	41	22 (53.7)	6.41 (1.35, N.A.)	1.783 (1.019, 3.120) 0.0411	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 3 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.4057
J/K/T	91	73 (80.2)	1.41 (0.72, 1.64)	85	46 (54.1)	5.59 (3.65, 7.95)	2.636 (1.802, 3.857) <0.0001	
REST OF ASIA	25	17 (68.0)	1.87 (0.49, 5.78)	19	11 (57.9)	3.94 (1.25, N.A.)	1.513 (0.704, 3.253) 0.2877	
REST OF WORLD	42	32 (76.2)	1.08 (0.76, 2.76)	41	22 (53.7)	6.41 (1.35, N.A.)	1.821 (1.045, 3.174) 0.0332	
REGION								0.5643
ASIA	116	90 (77.6)	1.41 (0.76, 1.71)	104	57 (54.8)	5.55 (3.65, 6.24)	2.351 (1.674, 3.302) <0.0001	
NON-ASIA	42	32 (76.2)	1.08 (0.76, 2.76)	41	22 (53.7)	6.41 (1.35, N.A.)	1.821 (1.045, 3.174) 0.0332	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 4 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6759
0	71	63 (88.7)	1.28 (0.56, 1.48)	69	42 (60.9)	4.63 (2.99, 7.36)	2.515 (1.678, 3.768) <0.0001	
1	87	59 (67.8)	1.45 (0.95, 2.30)	74	35 (47.3)	6.21 (2.79, N.A.)	2.106 (1.376, 3.224) 0.0005	
WEIGHT								0.8085
< 60 KG	96	75 (78.1)	1.45 (0.99, 1.87)	76	40 (52.6)	5.59 (2.79, 7.36)	2.231 (1.507, 3.303) <0.0001	
>= 60 KG	62	47 (75.8)	1.15 (0.62, 1.97)	69	39 (56.5)	4.63 (2.76, 7.95)	2.090 (1.357, 3.221) 0.0007	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 5 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.5515
STAGE I	5	5 (100.0)	1.97 (0.72, N.A.)	5	2 (40.0)	N.A. (3.65, N.A.)	4.145 (0.727, 23.641) 0.0860	
STAGE II	5	4 (80.0)	1.38 (0.10, N.A.)	5	3 (60.0)	5.55 (0.10, N.A.)	1.661 (0.361, 7.650) 0.5045	
STAGE III	33	24 (72.7)	1.87 (1.18, 3.75)	46	26 (56.5)	6.05 (1.97, N.A.)	1.505 (0.853, 2.656) 0.1599	
STAGE IV	114	88 (77.2)	1.15 (0.62, 1.48)	89	48 (53.9)	5.55 (2.99, 6.44)	2.410 (1.679, 3.460) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 6 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.4114
GX	11	7 (63.6)	2.76 (0.13, N.A.)	14	5 (35.7)	7.95 (4.17, N.A.)	8.136 (1.652, 40.072) 0.0025	
G1	8	7 (87.5)	1.07 (0.03, 2.30)	8	6 (75.0)	0.99 (0.07, N.A.)	1.381 (0.436, 4.377) 0.5552	
G2	58	44 (75.9)	1.41 (0.92, 1.87)	50	23 (46.0)	7.36 (2.79, N.A.)	2.729 (1.623, 4.589) <0.0001	
G3	28	22 (78.6)	0.74 (0.46, 3.75)	36	24 (66.7)	3.94 (1.91, 6.24)	1.533 (0.851, 2.763) 0.1613	
NOT OTHERWISE SPECIFIED	51	40 (78.4)	1.61 (0.92, 2.33)	37	21 (56.8)	5.55 (1.84, 6.41)	1.823 (1.065, 3.120) 0.0257	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 7 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.3803
UPPER THORACIC	37	30 (81.1)	1.45 (0.62, 2.69)	25	12 (48.0)	5.55 (0.95, N.A.)	2.308 (1.167, 4.566) 0.0138	
MIDDLE THORACIC	50	35 (70.0)	1.38 (0.62, 1.97)	52	25 (48.1)	5.75 (4.57, N.A.)	2.852 (1.684, 4.830) <0.0001	
LOWER THORACIC	59	47 (79.7)	1.38 (0.56, 1.87)	60	40 (66.7)	3.25 (1.45, 6.21)	1.657 (1.076, 2.551) 0.0197	
GASTROESOPHAGEAL JUNCTION	11	9 (81.8)	1.45 (0.46, N.A.)	8	2 (25.0)	N.A. (0.30, N.A.)	3.698 (0.777, 17.587) 0.0788	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 8 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.2413
RECURRENT - LOCO-REGIONAL	8	6 (75.0)	3.70 (0.46, N.A.)	13	9 (69.2)	3.65 (0.46, N.A.)	0.763 (0.255, 2.287) 0.6039	
RECURRENT - DISTANT	25	17 (68.0)	1.87 (0.99, 8.11)	27	13 (48.1)	6.05 (1.91, N.A.)	1.920 (0.925, 3.989) 0.0750	
DE NOVO METASTATIC	107	82 (76.6)	1.08 (0.62, 1.48)	81	46 (56.8)	4.57 (2.76, 6.41)	2.257 (1.556, 3.275) <0.0001	
UNRESECTABLE ADVANCED	18	17 (94.4)	1.23 (0.49, 2.14)	24	11 (45.8)	8.25 (1.97, N.A.)	3.371 (1.541, 7.375) 0.0013	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 9 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.4170
CURRENT/FORMER	136	109 (80.1)	1.41 (0.95, 1.61)	111	63 (56.8)	4.63 (3.22, 6.44)	2.276 (1.654, 3.131) <0.0001	
NEVER/UNKNOWN	22	13 (59.1)	2.92 (0.53, N.A.)	34	16 (47.1)	6.24 (1.97, N.A.)	1.531 (0.722, 3.243) 0.2659	
ALCOHOL USE								0.4555
CURRENT/FORMER	126	97 (77.0)	1.41 (0.95, 1.71)	117	66 (56.4)	4.63 (3.22, 6.44)	2.103 (1.525, 2.898) <0.0001	
NEVER/UNKNOWN	32	25 (78.1)	0.90 (0.49, 2.79)	28	13 (46.4)	6.41 (2.53, N.A.)	2.713 (1.374, 5.357) 0.0028	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 10 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.8206
<= 1	80	67 (83.8)	0.99 (0.56, 1.45)	69	43 (62.3)	4.17 (2.53, 6.41)	2.233 (1.509, 3.305) <0.0001	
>= 2	78	55 (70.5)	1.64 (1.28, 2.69)	76	36 (47.4)	5.75 (3.25, N.A.)	2.130 (1.387, 3.272) 0.0004	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.3282
< 1 YEAR	128	101 (78.9)	1.15 (0.72, 1.45)	115	64 (55.7)	5.55 (2.99, 6.44)	2.309 (1.674, 3.183) <0.0001	
1 - < 3 YEARS	25	16 (64.0)	3.65 (1.41, N.A.)	21	11 (52.4)	6.05 (1.84, N.A.)	1.821 (0.807, 4.111) 0.1463	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.4073
YES	38	29 (76.3)	1.45 (0.99, 2.30)	37	21 (56.8)	5.55 (1.91, 10.61)	1.758 (0.991, 3.118) 0.0516	
NO	120	93 (77.5)	1.28 (0.76, 1.64)	108	58 (53.7)	5.59 (3.22, 7.36)	2.340 (1.672, 3.275) <0.0001	
PRIOR RADIOTHERAPY								0.7039
YES	26	18 (69.2)	2.79 (1.41, 8.11)	27	11 (40.7)	10.61 (2.53, N.A.)	1.850 (0.861, 3.973) 0.1111	
NO	132	104 (78.8)	1.18 (0.72, 1.45)	118	68 (57.6)	4.63 (2.99, 6.41)	2.271 (1.657, 3.114) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 12 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.4932
< 10	53	42 (79.2)	1.61 (1.35, 2.33)	54	30 (55.6)	4.17 (2.46, 7.36)	1.987 (1.229, 3.212) 0.0044	
>= 10	92	70 (76.1)	1.28 (0.76, 1.71)	89	48 (53.9)	5.59 (3.12, 8.25)	2.195 (1.504, 3.203) <0.0001	
PD-L1 CPS II								0.1285
< 5	29	20 (69.0)	1.87 (1.38, 2.79)	24	14 (58.3)	2.46 (0.82, N.A.)	1.378 (0.693, 2.741) 0.3597	
>= 5	116	92 (79.3)	1.38 (0.92, 1.64)	119	64 (53.8)	5.75 (3.94, 7.36)	2.358 (1.699, 3.272) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

Protocol: CA209648 Page 13 of 13

Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.6495
< 10%	55	47 (85.5)	1.45 (0.95, 2.20)	57	29 (50.9)	5.55 (2.46, N.A.)	2.494 (1.551, 4.011) 0.0001	
>= 10%	103	75 (72.8)	1.28 (0.62, 1.71)	88	50 (56.8)	5.55 (3.22, 7.36)	2.017 (1.400, 2.907) 0.0001	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9968
< 5%	38	33 (86.8)	1.43 (0.76, 2.14)	41	24 (58.5)	4.17 (1.31, N.A.)	2.420 (1.382, 4.238) 0.0014	
>= 5%	120	89 (74.2)	1.41 (0.76, 1.87)	104	55 (52.9)	5.59 (3.75, 7.95)	2.172 (1.542, 3.061) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:11

4.3.1.8 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren spezifischen UE (CTCAE Grad ≥ 3)

Protocol: CA209648 Page 1 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	40 (25.3)	N.A. (14.55, N.A.)	145	11 (7.6)	N.A.	3.269 (1.669, 6.404) 0.0003	
AGE								0.5790
< 65	95	21 (22.1)	N.A. (14.55, N.A.)	75	6 (8.0)	N.A.	2.629 (1.053, 6.564) 0.0316	
>= 65 AND < 75	55	15 (27.3)	N.A. (9.66, N.A.)	58	3 (5.2)	N.A.	5.739 (1.659, 19.857) 0.0018	
>= 75	8	4 (50.0)	6.87 (0.95, N.A.)	12	2 (16.7)	N.A. (6.24, N.A.)	2.152 (0.386, 12.003) 0.3713	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 2 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5052
MALE	131	33 (25.2)	N.A. (12.98, N.A.)	122	10 (8.2)	N.A.	3.000 (1.469, 6.126) 0.0015	
FEMALE	27	7 (25.9)	N.A. (6.51, N.A.)	23	1 (4.3)	N.A. (11.07, N.A.)	6.105 (0.748, 49.819) 0.0542	
RACE								0.6431
ASIAN	117	31 (26.5)	N.A. (12.39, N.A.)	104	9 (8.7)	N.A.	3.039 (1.439, 6.417) 0.0022	
NON-ASIAN	41	9 (22.0)	N.A. (14.55, N.A.)	41	2 (4.9)	N.A. (11.07, N.A.)	4.077 (0.865, 19.220) 0.0553	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 3 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.8607
J/K/T	91	25 (27.5)	N.A. (12.39, N.A.)	85	8 (9.4)	N.A.	3.125 (1.401, 6.969) 0.0033	
REST OF ASIA	25	5 (20.0)	N.A. (12.98, N.A.)	19	1 (5.3)	N.A.	2.681 (0.299, 24.040) 0.3591	
REST OF WORLD	42	10 (23.8)	N.A. (9.66, N.A.)	41	2 (4.9)	N.A. (11.07, N.A.)	4.171 (0.896, 19.420) 0.0492	
REGION								0.5653
ASIA	116	30 (25.9)	N.A. (12.98, N.A.)	104	9 (8.7)	N.A.	3.004 (1.418, 6.360) 0.0025	
NON-ASIA	42	10 (23.8)	N.A. (9.66, N.A.)	41	2 (4.9)	N.A. (11.07, N.A.)	4.171 (0.896, 19.420) 0.0492	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 4 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6644
0	71	21 (29.6)	N.A. (12.39, N.A.)	69	7 (10.1)	N.A.	3.008 (1.278, 7.079) 0.0080	
1	87	19 (21.8)	N.A. (12.98, N.A.)	74	4 (5.4)	N.A. (11.07, N.A.)	3.530 (1.176, 10.599) 0.0167	
WEIGHT								0.1892
< 60 KG	96	24 (25.0)	N.A. (12.39, N.A.)	76	8 (10.5)	N.A. (11.07, N.A.)	2.115 (0.940, 4.759) 0.0637	
>= 60 KG	62	16 (25.8)	N.A.	69	3 (4.3)	N.A.	6.916 (2.014, 23.754) 0.0004	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 5 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9449
STAGE I	5	3 (60.0)	12.98 (5.59, N.A.)	5	0	N.E.	N.E. 0.2649	
STAGE II	5	2 (40.0)	6.87 (2.30, N.A.)	5	0	N.E.	N.E. 0.2087	
STAGE III	33	9 (27.3)	N.A. (12.39, N.A.)	46	5 (10.9)	N.A.	2.273 (0.749, 6.892) 0.1367	
STAGE IV	114	26 (22.8)	N.A.	89	6 (6.7)	N.A. (11.07, N.A.)	3.672 (1.508, 8.942) 0.0022	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 6 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.6180
GX	11	3 (27.3)	N.A. (0.95, N.A.)	14	0	N.E.	N.E. 0.0290	
G1	8	2 (25.0)	N.A. (6.54, N.A.)	8	0	N.E.	N.E. 0.3711	
G2	58	12 (20.7)	N.A. (14.55, N.A.)	50	2 (4.0)	N.A. (11.07, N.A.)	5.040 (1.122, 22.637) 0.0192	
G3	28	5 (17.9)	N.A. (9.66, N.A.)	36	5 (13.9)	N.A.	1.282 (0.369, 4.459) 0.6949	
NOT OTHERWISE SPECIFIED	51	18 (35.3)	12.39 (6.51, N.A.)	37	4 (10.8)	N.A.	3.231 (1.085, 9.621) 0.0255	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 7 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.2935
UPPER THORACIC	37	9 (24.3)	N.A. (12.39, N.A.)	25	2 (8.0)	N.A.	2.965 (0.637, 13.801) 0.1462	
MIDDLE THORACIC	50	17 (34.0)	8.25 (6.51, N.A.)	52	3 (5.8)	N.A. (11.07, N.A.)	7.813 (2.284, 26.725) 0.0001	
LOWER THORACIC	59	11 (18.6)	N.A.	60	6 (10.0)	N.A.	1.720 (0.629, 4.702) 0.2838	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	14.55 (9.66, N.A.)	8	0	N.E.	N.E. N.A.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 8 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
DISEASE STATUS AT CURRENT DIAGNOSIS								0.7184
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	19.12 (0.46, N.A.)	13	1 (7.7)	N.A.	2.254 (0.192, 26.530) 0.5085	
RECURRENT - DISTANT	25	7 (28.0)	12.98 (6.87, N.A.)	27	3 (11.1)	N.A.	1.715 (0.408, 7.208) 0.4564	
DE NOVO METASTATIC	107	24 (22.4)	N.A.	81	6 (7.4)	N.A. (11.07, N.A.)	3.316 (1.352, 8.130) 0.0055	
UNRESECTABLE ADVANCED	18	7 (38.9)	14.55 (5.52, N.A.)	24	1 (4.2)	N.A.	8.549 (1.048, 69.734) 0.0162	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 9 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9049
CURRENT/FORMER	136	36 (26.5)	N.A. (12.98, N.A.)	111	9 (8.1)	N.A.	3.143 (1.506, 6.562) 0.0013	
NEVER/UNKNOWN	22	4 (18.2)	N.A.	34	2 (5.9)	N.A. (11.07, N.A.)	3.664 (0.669, 20.056) 0.1089	
ALCOHOL USE								0.3421
CURRENT/FORMER	126	31 (24.6)	N.A. (19.12, N.A.)	117	10 (8.5)	N.A.	2.917 (1.424, 5.974) 0.0022	
NEVER/UNKNOWN	32	9 (28.1)	14.55 (6.87, N.A.)	28	1 (3.6)	N.A. (11.07, N.A.)	6.502 (0.807, 52.409) 0.0436	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 10 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.1994
<= 1	80	27 (33.8)	19.12 (9.66, N.A.)	69	5 (7.2)	N.A.	4.731 (1.813, 12.350) 0.0005	
>= 2	78	13 (16.7)	N.A.	76	6 (7.9)	N.A. (11.07, N.A.)	2.088 (0.790, 5.524) 0.1287	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.6176
< 1 YEAR	128	31 (24.2)	N.A.	115	9 (7.8)	N.A.	3.159 (1.498, 6.662) 0.0014	
1 - < 3 YEARS	25	5 (20.0)	N.A. (6.87, N.A.)	21	2 (9.5)	N.A.	1.773 (0.335, 9.367) 0.4946	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 11 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
PRIOR SURGERY (EXCLUDING BIOPSY)								0.1950
YES	38	8 (21.1)	N.A. (9.66, N.A.)	37	4 (10.8)	N.A.	1.439 (0.425, 4.875) 0.5571	
NO	120	32 (26.7)	N.A. (14.55, N.A.)	108	7 (6.5)	N.A.	4.432 (1.949, 10.080) 0.0001	
PRIOR RADIOTHERAPY								0.8319
YES	26	6 (23.1)	19.12 (6.87, N.A.)	27	2 (7.4)	N.A.	2.394 (0.471, 12.173) 0.2790	
NO	132	34 (25.8)	N.A. (14.55, N.A.)	118	9 (7.6)	N.A.	3.492 (1.668, 7.311) 0.0004	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 12 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.9875
< 10	53	14 (26.4)	19.12 (6.87, N.A.)	54	4 (7.4)	N.A.	3.153 (1.022, 9.730) 0.0352	
>= 10	92	24 (26.1)	N.A. (12.98, N.A.)	89	7 (7.9)	N.A.	3.387 (1.450, 7.914) 0.0028	
PD-L1 CPS II								0.0193*
< 5	29	4 (13.8)	N.A. (6.54, N.A.)	24	4 (16.7)	N.A.	0.777 (0.193, 3.135) 0.7224	
>= 5	116	34 (29.3)	N.A. (12.98, N.A.)	119	7 (5.9)	N.A.	4.870 (2.146, 11.051) <0.0001	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

Protocol: CA209648 Page 13 of 13

Select Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Select Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.3530
< 10%	55	12 (21.8)	N.A. (12.39, N.A.)	57	5 (8.8)	N.A. (11.07, N.A.)	2.052 (0.714, 5.897) 0.1730	
>= 10%	103	28 (27.2)	N.A. (12.98, N.A.)	88	6 (6.8)	N.A.	4.206 (1.730, 10.228) 0.0006	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.2517
< 5%	38	7 (18.4)	N.A. (6.54, N.A.)	41	4 (9.8)	N.A.	1.851 (0.541, 6.329) 0.3185	
>= 5%	120	33 (27.5)	N.A. (12.98, N.A.)	104	7 (6.7)	N.A.	4.034 (1.771, 9.189) 0.0003	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:15:41

4.3.1.9 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen UE

Protocol: CA209648 Page 1 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	37 (23.4)	N.A. (23.06, N.A.)	145	7 (4.8)	N.A.	4.727 (2.092, 10.680) <0.0001	
AGE								0.2707
< 65	95	18 (18.9)	N.A. (19.12, N.A.)	75	4 (5.3)	N.A.	3.092 (1.026, 9.316) 0.0348	
>= 65 AND < 75	55	15 (27.3)	N.A. (9.66, N.A.)	58	1 (1.7)	N.A.	18.152 (2.394,>99.999) 0.0001	
>= 75	8	4 (50.0)	6.87 (0.95, N.A.)	12	2 (16.7)	N.A. (6.24, N.A.)	2.357 (0.421, 13.189) 0.3157	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8909
MALE	131	32 (24.4)	25.63 (19.12, N.A.)	122	6 (4.9)	N.A.	4.852 (2.010, 11.712) 0.0001	
FEMALE	27	5 (18.5)	N.A. (8.15, N.A.)	23	1 (4.3)	N.A.	4.558 (0.532, 39.069) 0.1285	
RACE								0.3073
ASIAN	117	29 (24.8)	25.63 (19.12, N.A.)	104	4 (3.8)	N.A.	6.193 (2.159, 17.764) 0.0001	
NON-ASIAN	41	8 (19.5)	N.A. (14.55, N.A.)	41	3 (7.3)	N.A.	2.781 (0.732, 10.562) 0.1173	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 3 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION (PER CRF)								0.6974
J/K/T	91	25 (27.5)	25.63 (19.12, N.A.)	85	4 (4.7)	N.A.	5.787 (1.992, 16.810) 0.0003	
REST OF ASIA	25	3 (12.0)	N.A.	19	0	N.E.	N.E. 0.1587	
REST OF WORLD	42	9 (21.4)	N.A. (14.55, N.A.)	41	3 (7.3)	N.A.	2.819 (0.752, 10.558) 0.1088	
REGION								0.3665
ASIA	116	28 (24.1)	N.A. (23.06, N.A.)	104	4 (3.8)	N.A.	6.116 (2.127, 17.586) 0.0001	
NON-ASIA	42	9 (21.4)	N.A. (14.55, N.A.)	41	3 (7.3)	N.A.	2.819 (0.752, 10.558) 0.1088	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 4 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								0.6585
0	71	20 (28.2)	N.A.	69	4 (5.8)	N.A.	5.054 (1.727, 14.793) 0.0010	
1	87	17 (19.5)	25.63 (19.12, N.A.)	74	2 (2.7)	N.A.	6.234 (1.402, 27.720) 0.0061	
WEIGHT								0.5774
< 60 KG	96	20 (20.8)	N.A. (14.55, N.A.)	76	4 (5.3)	N.A.	3.780 (1.282, 11.142) 0.0096	
>= 60 KG	62	17 (27.4)	25.63 (23.06, N.A.)	69	3 (4.3)	N.A.	6.365 (1.841, 22.000) 0.0008	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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).
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Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 5 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								0.8100
STAGE I	5	2 (40.0)	19.12 (1.91, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	2 (40.0)	6.87 (2.30, N.A.)	5	0	N.E.	N.E. 0.2087	
STAGE III	33	9 (27.3)	N.A. (8.15, N.A.)	46	4 (8.7)	N.A.	2.956 (0.902, 9.685) 0.0608	
STAGE IV	114	24 (21.1)	N.A. (23.06, N.A.)	89	3 (3.4)	N.A.	6.439 (1.924, 21.552) 0.0005	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 6 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.2111
GX	11	2 (18.2)	N.A. (0.95, N.A.)	14	0	N.E.	N.E. 0.0766	
G1	8	1 (12.5)	N.A. (6.54, N.A.)	8	0	N.E.	N.E. 0.3711	
G2	58	18 (31.0)	23.06 (14.55, N.A.)	50	2 (4.0)	N.A.	7.188 (1.650, 31.316) 0.0021	
G3	28	3 (10.7)	N.A. (9.66, N.A.)	36	4 (11.1)	N.A.	0.945 (0.209, 4.276) 0.9416	
NOT OTHERWISE SPECIFIED	51	13 (25.5)	19.12 (19.12, N.A.)	37	1 (2.7)	N.A. (6.97, N.A.)	9.926 (1.288, 76.497) 0.0067	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 7 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.1865
UPPER THORACIC	37	8 (21.6)	23.06 (23.06, N.A.)	25	0	N.E.	N.E. 0.0294	
MIDDLE THORACIC	50	17 (34.0)	25.63 (3.84, N.A.)	52	2 (3.8)	N.A.	10.773 (2.471, 46.955) <0.0001	
LOWER THORACIC	59	8 (13.6)	N.A.	60	5 (8.3)	N.A.	1.628 (0.532, 4.984) 0.3905	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	14.55 (9.66, N.A.)	8	0	N.E.	N.E. N.A.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 8 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.6982
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	19.12 (0.46, N.A.)	13	1 (7.7)	N.A.	2.373 (0.200, 28.111) 0.4823	
RECURRENT - DISTANT	25	6 (24.0)	N.A. (6.87, N.A.)	27	3 (11.1)	N.A.	2.147 (0.534, 8.625) 0.2702	
DE NOVO METASTATIC	107	22 (20.6)	N.A. (23.06, N.A.)	81	3 (3.7)	N.A.	6.168 (1.838, 20.697) 0.0008	
UNRESECTABLE ADVANCED	18	7 (38.9)	14.55 (8.15, N.A.)	24	0	N.E.	N.E. 0.0148	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 9 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.2102
CURRENT/FORMER	136	35 (25.7)	25.63 (19.12, N.A.)	111	5 (4.5)	N.A.	5.504 (2.140, 14.151) <0.0001	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	2 (5.9)	N.A.	1.627 (0.229, 11.578) 0.6235	
ALCOHOL USE								0.1801
CURRENT/FORMER	126	33 (26.2)	25.63 (19.12, N.A.)	117	5 (4.3)	N.A.	6.136 (2.380, 15.822) <0.0001	
NEVER/UNKNOWN	32	4 (12.5)	N.A. (14.55, N.A.)	28	2 (7.1)	N.A.	1.459 (0.258, 8.269) 0.6676	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 10 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.0557
<= 1	80	29 (36.3)	19.12 (8.15, N.A.)	69	3 (4.3)	N.A.	8.872 (2.688, 29.277) <0.0001	
>= 2	78	8 (10.3)	N.A. (25.63, N.A.)	76	4 (5.3)	N.A.	1.765 (0.516, 6.040) 0.3587	
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.2037
< 1 YEAR	128	30 (23.4)	N.A. (23.06, N.A.)	115	5 (4.3)	N.A.	5.252 (2.022, 13.644) 0.0001	
1 - < 3 YEARS	25	4 (16.0)	N.A. (6.87, N.A.)	21	2 (9.5)	N.A.	1.658 (0.303, 9.068) 0.5555	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 11 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SURGERY (EXCLUDING BIOPSY)								0.2054
YES	38	8 (21.1)	N.A. (9.66, N.A.)	37	3 (8.1)	N.A.	2.138 (0.558, 8.189) 0.2566	
NO	120	29 (24.2)	N.A. (23.06, N.A.)	108	4 (3.7)	N.A.	6.715 (2.345, 19.228) <0.0001	
PRIOR RADIOTHERAPY								0.6231
YES	26	7 (26.9)	N.A. (6.87, N.A.)	27	2 (7.4)	N.A.	3.314 (0.679, 16.178) 0.1171	
NO	132	30 (22.7)	N.A. (23.06, N.A.)	118	5 (4.2)	N.A.	5.338 (2.055, 13.863) 0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 12 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								0.4379
< 10	53	15 (28.3)	25.63 (6.87, N.A.)	54	2 (3.7)	N.A.	6.625 (1.492, 29.424) 0.0041	
>= 10	92	19 (20.7)	N.A. (23.06, N.A.)	89	5 (5.6)	N.A.	3.711 (1.371, 10.044) 0.0057	
PD-L1 CPS II								0.2577
< 5	29	5 (17.2)	25.63 (6.54, N.A.)	24	2 (8.3)	N.A.	1.512 (0.274, 8.341) 0.6328	
>= 5	116	29 (25.0)	N.A. (19.12, N.A.)	119	5 (4.2)	N.A.	5.853 (2.250, 15.227) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslae2-ebr503.sas 05MAR2022:08:16:13

Protocol: CA209648 Page 13 of 13

Serious Select Adverse Events: Subgroup Time-Adjusted Analyses
Any Select AEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Select Adverse Events Category: Any Select Adverse Events

Serious Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.4016
< 10%	55	14 (25.5)	25.63 (25.63, N.A.)	57	4 (7.0)	N.A.	3.274 (1.064, 10.071) 0.0286	
>= 10%	103	23 (22.3)	N.A. (19.12, N.A.)	88	3 (3.4)	N.A.	6.533 (1.943, 21.966) 0.0005	
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.0841
< 5%	38	8 (21.1)	25.63 (8.15, N.A.)	41	4 (9.8)	N.A.	1.777 (0.518, 6.096) 0.3542	
>= 5%	120	29 (24.2)	N.A. (19.12, N.A.)	104	3 (2.9)	N.A.	8.568 (2.593, 28.305) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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4.3.2 Zusatzanalysen: Spezifische immunvermittelte UE (imUE)

4.3.2.1 Zeit bis zum ersten Auftreten von jeglichen spezifischen imUE

Protocol: CA209648 Page 1 of 2

Immune-mediated Adverse Events: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH ANY IMAES	158	71 (44.9)	8.11 (4.11, 19.12)	145	4 (2.8)	N.A.	22.459 (8.182, 61.651)	<0.0001
SUBJECTS WITH DIARRHEA/COLITIS IMAES	158	6 (3.8)	N.A.	145	0	N.E.	N.E.	0.0177
SUBJECTS WITH HEPATITIS IMAES	158	8 (5.1)	N.A.	145	0	N.E.	N.E.	0.0111
SUBJECTS WITH HYPERSENSITIVITY IMAES	158	1 (0.6)	N.A.	145	0	N.E.	N.E.	0.3101
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION IMAES	158	4 (2.5)	N.A.	145	0	N.E.	N.E.	0.0538
SUBJECTS WITH PNEUMONITIS IMAES	158	8 (5.1)	N.A.	145	0	N.E.	N.E.	0.0121
SUBJECTS WITH RASH IMAES	158	27 (17.1)	N.A.	145	3 (2.1)	N.A.	9.490 (2.876, 31.318)	<0.0001

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr503.sas 08FEB2022:09:42:26

Protocol: CA209648 Page 2 of 2

Immune-mediated Adverse Events: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH ENDOCRINE IMAES	158	45 (28.5)	N.A. (14.55, N.A.)	145	1 (0.7)	N.A.	48.303 (6.651,>99.999)	<0.0001
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	158	12 (7.6)	N.A.	145	0	N.E.	N.E.	0.0018
SUBJECTS WITH DIABETES MELLITUS IMAES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.1542
SUBJECTS WITH HYPERTHYROIDISM IMAES	158	12 (7.6)	N.A.	145	1 (0.7)	N.A.	12.083 (1.568, 93.103)	0.0023
SUBJECTS WITH HYPOPHYSITIS IMAES	158	14 (8.9)	N.A.	145	0	N.E.	N.E.	0.0009
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	158	27 (17.1)	N.A.	145	0	N.E.	N.E.	<0.0001

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr503.sas 08FEB2022:09:42:26

4.3.2.2 Zeit bis zum ersten Auftreten von schweren spezifischen imUE (CTCAE Grad ≥ 3)

Protocol: CA209648 Page 1 of 2

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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	158	29 (18.4)	N.A.	145	1 (0.7)	N.A.	27.755 (3.768,>99.999)	<0.0001
SUBJECTS WITH DIARRHEA/COLITIS IMAES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.1036
SUBJECTS WITH HEPATITIS IMAES	158	6 (3.8)	N.A.	145	0	N.E.	N.E.	0.0164
SUBJECTS WITH HYPERSENSITIVITY IMAES	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION IMAES	158	2 (1.3)	N.A.	145	0	N.E.	N.E.	0.1493
SUBJECTS WITH PNEUMONITIS IMAES	158	6 (3.8)	N.A.	145	0	N.E.	N.E.	0.0335
SUBJECTS WITH RASH IMAES	158	5 (3.2)	N.A.	145	1 (0.7)	N.A.	4.973 (0.580, 42.663)	0.1045

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr503.sas 08FEB2022:09:42:43

Protocol: CA209648 Page 2 of 2

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH ENDOCRINE IMAES	158	11 (7.0)	N.A.	145	0	N.E.	N.E.	0.0023
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	158	5 (3.2)	N.A.	145	0	N.E.	N.E.	0.0339
SUBJECTS WITH DIABETES MELLITUS IMAES	158	2 (1.3)	N.A.	145	0	N.E.	N.E.	0.2699
SUBJECTS WITH HYPERTHYROIDISM IMAES	158	2 (1.3)	N.A.	145	0	N.E.	N.E.	0.1601
SUBJECTS WITH HYPOPHYSITIS IMAES	158	5 (3.2)	N.A.	145	0	N.E.	N.E.	0.0673
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	158	0	N.E.	145	0	N.E.	N.E.	N.E.

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr503.sas 08FEB2022:09:42:43

4.3.2.3 Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen imUE

Protocol: CA209648 Page 1 of 2

Serious Immune-mediated Adverse Events: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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	158	33 (20.9)	N.A. (23.06, N.A.)	145	0	N.E.	N.E.	<0.0001
SUBJECTS WITH DIARRHEA/COLITIS IMAES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.1036
SUBJECTS WITH HEPATITIS IMAES	158	4 (2.5)	N.A.	145	0	N.E.	N.E.	0.0531
SUBJECTS WITH HYPERSENSITIVITY IMAES	158	1 (0.6)	N.A.	145	0	N.E.	N.E.	0.3101
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION IMAES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.1022
SUBJECTS WITH PNEUMONITIS IMAES	158	8 (5.1)	N.A.	145	0	N.E.	N.E.	0.0121
SUBJECTS WITH RASH IMAES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.0860

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr503.sas 08FEB2022:09:43:00

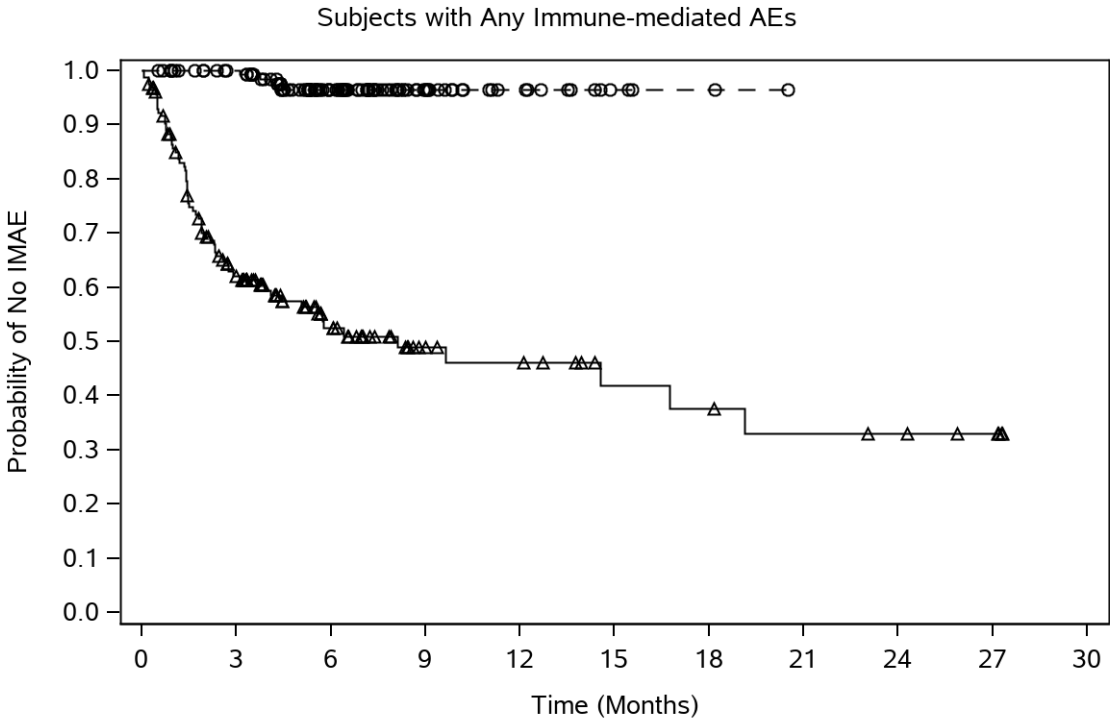
Protocol: CA209648 Page 2 of 2

Serious Immune-mediated Adverse Events: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH ENDOCRINE IMAES	158	16 (10.1)	N.A.	145	0	N.E.	N.E.	0.0003
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	158	7 (4.4)	N.A.	145	0	N.E.	N.E.	0.0115
SUBJECTS WITH DIABETES MELLITUS IMAES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.1542
SUBJECTS WITH HYPERTHYROIDISM IMAES	158	2 (1.3)	N.A.	145	0	N.E.	N.E.	0.1601
SUBJECTS WITH HYPOPHYSITIS IMAES	158	8 (5.1)	N.A.	145	0	N.E.	N.E.	0.0227
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.0859

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2)
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-imaetahrt-ebr503.sas 08FEB2022:09:43:00

4.3.2.4 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen spezifischen imUE



Number of Subjects at Risk

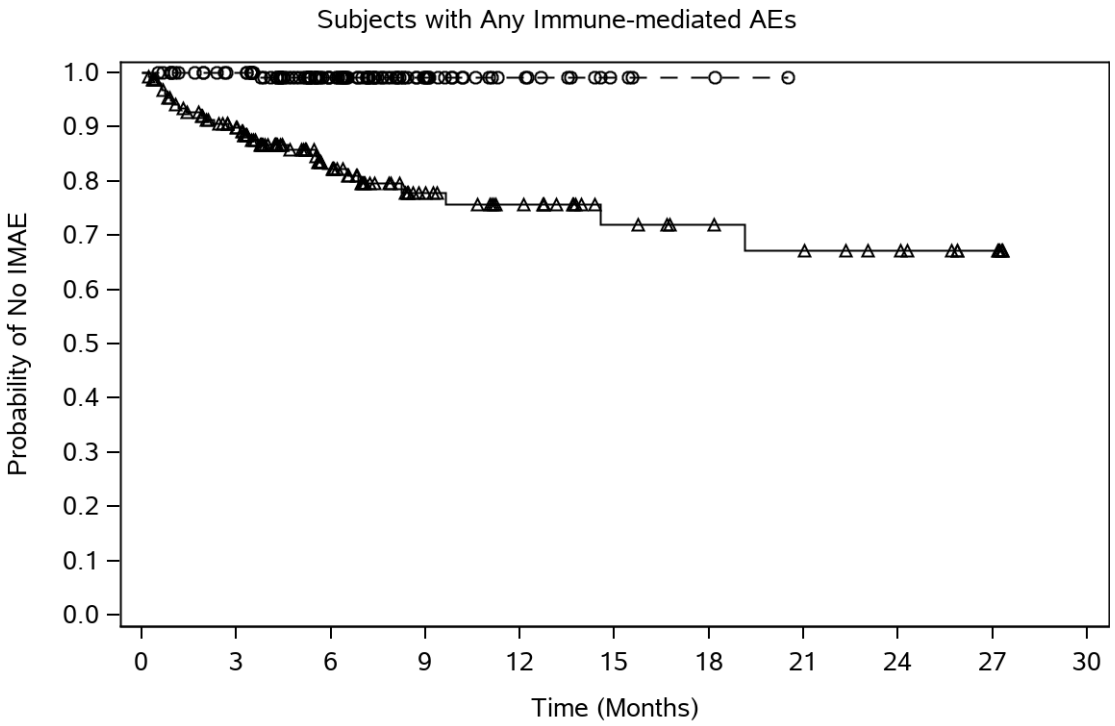
Nivo + Ipi	158	82	39	19	16	10	9	7	6	4	0
Chemo	145	132	66	26	12	4	2	0	0	0	0

Nivo + Ipi (events: 71/158), median and 95% CI: 8.11 (4.11, 19.12)

Chemo (events: 4/145), median and 95% CI: N.A.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 22.459 (8.182, 61.651), p-value: <0.0001

4.3.2.5 KM-Kurven – Zeit bis zum ersten Auftreten von schweren spezifischen imUE (CTCAE Grad ≥ 3)



Number of Subjects at Risk

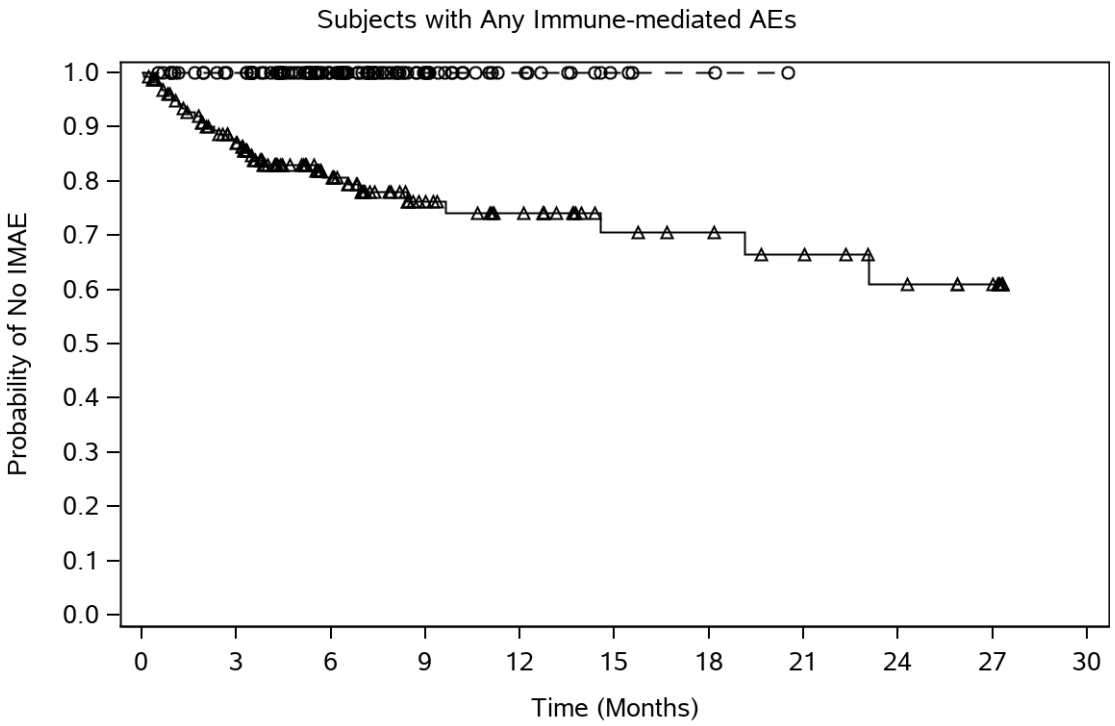
Nivo + Ipi	158	121	69	39	30	19	16	14	11	6	0
Chemo	145	132	68	27	12	4	2	0	0	0	0

Nivo + Ipi (events: 29/158), median and 95% CI: N.A.

Chemo (events: 1/145), median and 95% CI: N.A.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: 27.755 (3.768, >99.999), p-value: <0.0001

4.3.2.6 KM-Kurven – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen imUE



Number of Subjects at Risk

Nivo + Ipi	158	117	67	39	31	20	18	15	11	8	0
Chemo	145	132	68	27	12	4	2	0	0	0	0

Nivo + Ipi (events: 33/158), median and 95% CI: N.A. (23.06, N.A.)

Chemo (events: 0/145), median and 95% CI: N.E.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: N.E., p-value: <0.0001

4.3.2.7 Subgruppenanalysen – Zeit bis zum ersten Auftreten von jeglichen spezifischen imUE

Protocol: CA209648 Page 1 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	71 (44.9)	8.11 (4.11, 19.12)	145	4 (2.8)	N.A.	22.011 (8.027, 60.355) <0.0001	
AGE								0.4863
< 65	95	37 (38.9)	16.76 (5.75, N.A.)	75	3 (4.0)	N.A.	12.126 (3.728, 39.448) <0.0001	
>= 65 AND < 75	55	30 (54.5)	4.11 (1.91, N.A.)	58	1 (1.7)	N.A.	54.182 (7.341,>99.999) <0.0001	
>= 75	8	4 (50.0)	N.A. (0.72, N.A.)	12	0	N.E.	N.E. 0.0073	
SEX								0.9882
MALE	131	60 (45.8)	6.41 (4.11, 16.76)	122	4 (3.3)	N.A.	19.018 (6.896, 52.452) <0.0001	
FEMALE	27	11 (40.7)	N.A. (1.61, N.A.)	23	0	N.E.	N.E. 0.0006	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 2 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9627
ASIAN	117	55 (47.0)	5.78 (3.12, 19.12)	104	3 (2.9)	N.A.	22.516 (7.030, 72.113) <0.0001	
NON-ASIAN	41	16 (39.0)	14.55 (2.76, N.A.)	41	1 (2.4)	N.A.	20.238 (2.665,>99.999) <0.0001	
REGION (PER CRF)								0.9999
J/K/T	91	47 (51.6)	5.06 (2.33, 19.12)	85	3 (3.5)	N.A.	21.615 (6.707, 69.658) <0.0001	
REST OF ASIA	25	7 (28.0)	N.A. (5.78, N.A.)	19	0	N.E.	N.E. 0.0175	
REST OF WORLD	42	17 (40.5)	14.55 (3.75, N.A.)	41	1 (2.4)	N.A.	20.068 (2.652,>99.999) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 3 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9786
ASIA	116	54 (46.6)	5.78 (3.12, N.A.)	104	3 (2.9)	N.A.	22.361 (6.980, 71.633) <0.0001	
NON-ASIA	42	17 (40.5)	14.55 (3.75, N.A.)	41	1 (2.4)	N.A.	20.068 (2.652,>99.999) <0.0001	
ECOG PS (PER CRF)								0.5561
0	71	39 (54.9)	5.75 (1.97, N.A.)	69	3 (4.3)	N.A.	17.469 (5.388, 56.638) <0.0001	
1	87	32 (36.8)	14.55 (4.47, N.A.)	74	1 (1.4)	N.A.	35.799 (4.873,>99.999) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 4 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
WEIGHT								0.3510
< 60 KG	96	42 (43.8)	8.11 (3.75, 19.12)	76	1 (1.3)	N.A.	44.321 (6.091,>99.999) <0.0001	
>= 60 KG	62	29 (46.8)	6.41 (2.76, N.A.)	69	3 (4.3)	N.A.	14.712 (4.471, 48.415) <0.0001	
DISEASE STAGE AT INITIAL DIAGNOSIS								0.9291
STAGE I	5	4 (80.0)	2.76 (1.91, N.A.)	5	0	N.E.	N.E. 0.0494	
STAGE II	5	3 (60.0)	2.73 (1.81, N.A.)	5	0	N.E.	N.E. 0.1269	
STAGE III	33	16 (48.5)	14.55 (2.17, N.A.)	46	2 (4.3)	N.A.	13.198 (3.005, 57.967) <0.0001	
STAGE IV	114	48 (42.1)	6.41 (4.47, N.A.)	89	2 (2.2)	N.A.	26.917 (6.532,>99.999) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 5 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								0.9314
GX	11	4 (36.4)	N.A. (0.23, N.A.)	14	0	N.E.	N.E. 0.0063	
G1	8	3 (37.5)	N.A. (0.79, N.A.)	8	0	N.E.	N.E. 0.0486	
G2	58	30 (51.7)	5.55 (1.91, N.A.)	50	1 (2.0)	N.A.	36.187 (4.927,>99.999) <0.0001	
G3	28	11 (39.3)	9.66 (4.11, N.A.)	36	1 (2.8)	N.A.	17.154 (2.187,>99.999) 0.0002	
NOT OTHERWISE SPECIFIED	51	23 (45.1)	8.11 (2.17, N.A.)	37	2 (5.4)	N.A.	11.021 (2.586, 46.967) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 6 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								0.9970
UPPER THORACIC	37	20 (54.1)	5.06 (1.91, N.A.)	25	1 (4.0)	N.A.	18.128 (2.427,>99.999) <0.0001	
MIDDLE THORACIC	50	24 (48.0)	3.91 (1.81, N.A.)	52	3 (5.8)	N.A.	13.216 (3.950, 44.222) <0.0001	
LOWER THORACIC	59	20 (33.9)	N.A. (5.75, N.A.)	60	0	N.E.	N.E. <0.0001	
GASTROESOPHAGEAL JUNCTION	11	6 (54.5)	14.55 (1.15, N.A.)	8	0	N.E.	N.E. 0.1462	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 7 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STATUS AT CURRENT DIAGNOSIS								0.8250
RECURRENT - LOCO-REGIONAL	8	5 (62.5)	16.76 (0.72, N.A.)	13	0	N.E.	N.E. 0.0123	
RECURRENT - DISTANT	25	11 (44.0)	8.11 (1.97, N.A.)	27	0	N.E.	N.E. 0.0001	
DE NOVO METASTATIC	107	44 (41.1)	6.41 (4.47, N.A.)	81	2 (2.5)	N.A.	24.054 (5.821, 99.392) <0.0001	
UNRESECTABLE ADVANCED	18	11 (61.1)	4.11 (1.91, N.A.)	24	2 (8.3)	N.A.	9.452 (2.072, 43.120) 0.0005	
SMOKING STATUS								0.9873
CURRENT/FORMER	136	67 (49.3)	5.75 (3.12, 14.55)	111	4 (3.6)	N.A.	19.042 (6.928, 52.339) <0.0001	
NEVER/UNKNOWN	22	4 (18.2)	N.A.	34	0	N.E.	N.E. 0.0079	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 8 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.6752
CURRENT/FORMER	126	58 (46.0)	8.11 (3.75, 19.12)	117	3 (2.6)	N.A.	24.263 (7.587, 77.588) <0.0001	
NEVER/UNKNOWN	32	13 (40.6)	14.55 (2.76, N.A.)	28	1 (3.6)	N.A.	14.932 (1.944,>99.999) 0.0006	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.6844
<= 1	80	46 (57.5)	4.11 (2.37, 8.11)	69	3 (4.3)	N.A.	19.921 (6.178, 64.232) <0.0001	
>= 2	78	25 (32.1)	N.A. (6.41, N.A.)	76	1 (1.3)	N.A.	29.756 (4.023,>99.999) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 9 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9831
< 1 YEAR	128	56 (43.8)	6.41 (4.11, N.A.)	115	4 (3.5)	N.A.	17.708 (6.410, 48.920) <0.0001	
1 - < 3 YEARS	25	11 (44.0)	8.11 (2.56, N.A.)	21	0	N.E.	N.E. 0.0013	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9851
YES	38	18 (47.4)	9.66 (2.73, N.A.)	37	0	N.E.	N.E. <0.0001	
NO	120	53 (44.2)	6.41 (3.91, N.A.)	108	4 (3.7)	N.A.	16.875 (6.092, 46.745) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 10 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9871
YES	26	14 (53.8)	8.11 (1.81, 19.12)	27	0	N.E.	N.E. <0.0001	
NO	132	57 (43.2)	9.66 (4.47, N.A.)	118	4 (3.4)	N.A.	17.803 (6.448, 49.152) <0.0001	
PD-L1 CPS I								0.5516
< 10	53	26 (49.1)	5.75 (1.91, N.A.)	54	1 (1.9)	N.A.	35.304 (4.772,>99.999) <0.0001	
>= 10	92	39 (42.4)	9.66 (4.47, N.A.)	89	3 (3.4)	N.A.	17.111 (5.273, 55.524) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 11 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.9832
< 5	29	11 (37.9)	N.A. (1.81, N.A.)	24	0	N.E.	N.E. 0.0005	
>= 5	116	54 (46.6)	6.41 (4.11, 16.76)	119	4 (3.4)	N.A.	18.820 (6.798, 52.103) <0.0001	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9813
< 10%	55	27 (49.1)	8.11 (1.91, N.A.)	57	0	N.E.	N.E. <0.0001	
>= 10%	103	44 (42.7)	9.66 (5.06, 19.12)	88	4 (4.5)	N.A.	12.826 (4.589, 35.849) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:47:21

Protocol: CA209648 Page 12 of 12

Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9842
< 5%	38	18 (47.4)	N.A. (1.71, N.A.)	41	0	N.E.	N.E. <0.0001	
>= 5%	120	53 (44.2)	8.11 (4.47, 19.12)	104	4 (3.8)	N.A.	15.488 (5.588, 42.927) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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4.3.2.8 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schweren spezifischen imUE (CTCAE Grad ≥ 3)

Protocol: CA209648 Page 1 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	29 (18.4)	N.A.	145	1 (0.7)	N.A.	27.166 (3.693,>99.999) <0.0001	
AGE								0.9999
< 65	95	14 (14.7)	N.A. (19.12, N.A.)	75	1 (1.3)	N.A.	11.123 (1.455, 85.047) 0.0036	
>= 65 AND < 75	55	12 (21.8)	N.A. (9.66, N.A.)	58	0	N.E.	N.E. 0.0002	
>= 75	8	3 (37.5)	N.A. (2.76, N.A.)	12	0	N.E.	N.E. 0.0649	
SEX								0.9894
MALE	131	25 (19.1)	N.A. (19.12, N.A.)	122	1 (0.8)	N.A.	23.641 (3.193,>99.999) <0.0001	
FEMALE	27	4 (14.8)	N.A.	23	0	N.E.	N.E. 0.0573	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:48:13

Protocol: CA209648 Page 2 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9905
ASIAN	117	22 (18.8)	N.A. (19.12, N.A.)	104	1 (1.0)	N.A.	20.277 (2.726,>99.999) <0.0001	
NON-ASIAN	41	7 (17.1)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.0108	
REGION (PER CRF)								>0.9999
J/K/T	91	19 (20.9)	N.A. (19.12, N.A.)	85	1 (1.2)	N.A.	19.445 (2.595,>99.999) <0.0001	
REST OF ASIA	25	2 (8.0)	N.A.	19	0	N.E.	N.E. 0.2650	
REST OF WORLD	42	8 (19.0)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.0101	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 3 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9903
ASIA	116	21 (18.1)	N.A.	104	1 (1.0)	N.A.	19.893 (2.669,>99.999) <0.0001	
NON-ASIA	42	8 (19.0)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.0101	
ECOG PS (PER CRF)								0.9875
0	71	15 (21.1)	N.A.	69	1 (1.4)	N.A.	15.730 (2.078,>99.999) 0.0003	
1	87	14 (16.1)	N.A. (19.12, N.A.)	74	0	N.E.	N.E. 0.0011	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 4 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
WEIGHT								0.9916
< 60 KG	96	16 (16.7)	N.A. (19.12, N.A.)	76	0	N.E.	N.E. 0.0005	
>= 60 KG	62	13 (21.0)	N.A.	69	1 (1.4)	N.A.	16.406 (2.144,>99.999) 0.0003	
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	2 (40.0)	19.12 (5.59, N.A.)	5	0	N.E.	N.E. 0.3865	
STAGE II	5	2 (40.0)	6.87 (2.30, N.A.)	5	0	N.E.	N.E. 0.2087	
STAGE III	33	7 (21.2)	N.A. (14.55, N.A.)	46	0	N.E.	N.E. 0.0022	
STAGE IV	114	18 (15.8)	N.A.	89	1 (1.1)	N.A.	15.460 (2.060,>99.999) 0.0004	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 5 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								>0.9999
GX	11	2 (18.2)	N.A. (3.12, N.A.)	14	0	N.E.	N.E. 0.0731	
G1	8	1 (12.5)	N.A. (6.54, N.A.)	8	0	N.E.	N.E. 0.3711	
G2	58	11 (19.0)	N.A. (14.55, N.A.)	50	0	N.E.	N.E. 0.0022	
G3	28	3 (10.7)	N.A. (9.66, N.A.)	36	0	N.E.	N.E. 0.0513	
NOT OTHERWISE SPECIFIED	51	12 (23.5)	19.12 (19.12, N.A.)	37	1 (2.7)	N.A.	9.072 (1.169, 70.416) 0.0104	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 6 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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)
LOCATION AT INITIAL DIAGNOSIS								>0.9999
UPPER THORACIC	37	6 (16.2)	N.A.	25	0	N.E.	N.E. 0.0372	
MIDDLE THORACIC	50	14 (28.0)	N.A. (6.87, N.A.)	52	1 (1.9)	N.A.	18.228 (2.395,>99.999) 0.0001	
LOWER THORACIC	59	6 (10.2)	N.A.	60	0	N.E.	N.E. 0.0132	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	14.55 (9.66, N.A.)	8	0	N.E.	N.E. N.A.	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 7 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	19.12 (0.72, N.A.)	13	0	N.E.	N.E. 0.1698	
RECURRENT - DISTANT	25	5 (20.0)	N.A. (6.87, N.A.)	27	0	N.E.	N.E. 0.0206	
DE NOVO METASTATIC	107	16 (15.0)	N.A.	81	1 (1.2)	N.A.	13.669 (1.812,>99.999) 0.0009	
UNRESECTABLE ADVANCED	18	6 (33.3)	14.55 (5.52, N.A.)	24	0	N.E.	N.E. 0.0086	
SMOKING STATUS								0.9916
CURRENT/FORMER	136	26 (19.1)	N.A. (19.12, N.A.)	111	1 (0.9)	N.A.	21.320 (2.885,>99.999) <0.0001	
NEVER/UNKNOWN	22	3 (13.6)	N.A.	34	0	N.E.	N.E. 0.0200	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 8 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ALCOHOL USE								0.9925
CURRENT/FORMER	126	24 (19.0)	N.A.	117	1 (0.9)	N.A.	23.430 (3.163,>99.999) <0.0001	
NEVER/UNKNOWN	32	5 (15.6)	N.A. (14.55, N.A.)	28	0	N.E.	N.E. 0.0582	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9899
<= 1	80	22 (27.5)	N.A. (14.55, N.A.)	69	1 (1.4)	N.A.	19.938 (2.680,>99.999) <0.0001	
>= 2	78	7 (9.0)	N.A.	76	0	N.E.	N.E. 0.0069	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:48:13

Protocol: CA209648 Page 9 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9904
< 1 YEAR	128	23 (18.0)	N.A.	115	1 (0.9)	N.A.	21.583 (2.908,>99.999) <0.0001	
1 - < 3 YEARS	25	3 (12.0)	N.A. (6.87, N.A.)	21	0	N.E.	N.E. 0.1000	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9911
YES	38	7 (18.4)	N.A. (9.66, N.A.)	37	0	N.E.	N.E. 0.0208	
NO	120	22 (18.3)	N.A.	108	1 (0.9)	N.A.	21.980 (2.958,>99.999) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:48:13

Protocol: CA209648 Page 10 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
Subgroup	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9924
YES	26	5 (19.2)	N.A. (6.87, N.A.)	27	0	N.E.	N.E. 0.0347	
NO	132	24 (18.2)	N.A.	118	1 (0.8)	N.A.	22.609 (3.053,>99.999) <0.0001	
PD-L1 CPS I								0.9896
< 10	53	10 (18.9)	N.A. (19.12, N.A.)	54	0	N.E.	N.E. 0.0023	
>= 10	92	17 (18.5)	N.A.	89	1 (1.1)	N.A.	17.741 (2.355,>99.999) 0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:48:13

Protocol: CA209648 Page 11 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5 Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS II								0.9908
< 5	29	3 (10.3)	N.A. (6.54, N.A.)	24	0	N.E.	N.E. 0.1366	
>= 5	116	24 (20.7)	N.A. (19.12, N.A.)	119	1 (0.8)	N.A.	25.091 (3.384,>99.999) <0.0001	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								0.9896
< 10%	55	8 (14.5)	N.A.	57	0	N.E.	N.E. 0.0071	
>= 10%	103	21 (20.4)	N.A. (19.12, N.A.)	88	1 (1.1)	N.A.	19.322 (2.588,>99.999) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:48:13

Protocol: CA209648 Page 12 of 12

Immune-mediated Adverse Events with CTCAE Grade 3-4-5: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Immune-mediated Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
Subgroup								
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9915
< 5%	38	4 (10.5)	N.A.	41	0	N.E.	N.E. 0.0353	
>= 5%	120	25 (20.8)	N.A. (19.12, N.A.)	104	1 (1.0)	N.A.	22.771 (3.075,>99.999) <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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4.3.2.9 Subgruppenanalysen – Zeit bis zum ersten Auftreten von schwerwiegenden spezifischen imUE

Protocol: CA209648 Page 1 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	158	33 (20.9)	N.A. (23.06, N.A.)	145	0	N.E.	N.E. <0.0001	
AGE								>0.9999
< 65	95	15 (15.8)	N.A. (19.12, N.A.)	75	0	N.E.	N.E. 0.0010	
>= 65 AND < 75	55	15 (27.3)	N.A. (9.66, N.A.)	58	0	N.E.	N.E. <0.0001	
>= 75	8	3 (37.5)	N.A. (2.40, N.A.)	12	0	N.E.	N.E. 0.0454	
SEX								>0.9999
MALE	131	28 (21.4)	N.A. (19.12, N.A.)	122	0	N.E.	N.E. <0.0001	
FEMALE	27	5 (18.5)	N.A. (8.41, N.A.)	23	0	N.E.	N.E. 0.0360	

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HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

Protocol: CA209648 Page 2 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
RACE								0.9999
ASIAN	117	26 (22.2)	N.A. (19.12, N.A.)	104	0	N.E.	N.E. <0.0001	
NON-ASIAN	41	7 (17.1)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.0071	
REGION (PER CRF)								>0.9999
J/K/T	91	22 (24.2)	N.A. (19.12, N.A.)	85	0	N.E.	N.E. <0.0001	
REST OF ASIA	25	3 (12.0)	N.A.	19	0	N.E.	N.E. 0.1587	
REST OF WORLD	42	8 (19.0)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.0068	
REGION								>0.9999
ASIA	116	25 (21.6)	N.A. (23.06, N.A.)	104	0	N.E.	N.E. <0.0001	
NON-ASIA	42	8 (19.0)	N.A. (14.55, N.A.)	41	0	N.E.	N.E. 0.0068	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 3 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PS (PER CRF)								>0.9999
0	71	17 (23.9)	N.A.	69	0	N.E.	N.E. <0.0001	
1	87	16 (18.4)	N.A. (19.12, N.A.)	74	0	N.E.	N.E. 0.0005	
WEIGHT								0.9998
< 60 KG	96	17 (17.7)	N.A. (14.55, N.A.)	76	0	N.E.	N.E. 0.0004	
>= 60 KG	62	16 (25.8)	N.A. (23.06, N.A.)	69	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

Protocol: CA209648 Page 4 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT INITIAL DIAGNOSIS								>0.9999
STAGE I	5	2 (40.0)	19.12 (1.91, N.A.)	5	0	N.E.	N.E. 0.3173	
STAGE II	5	2 (40.0)	6.87 (2.30, N.A.)	5	0	N.E.	N.E. 0.2087	
STAGE III	33	7 (21.2)	N.A. (8.41, N.A.)	46	0	N.E.	N.E. 0.0036	
STAGE IV	114	22 (19.3)	N.A. (23.06, N.A.)	89	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
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Protocol: CA209648 Page 5 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Chemotherapy N	Subjects with Event n (%)	KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
HISTOLOGIC GRADE AT INITIAL DIAGNOSIS								>0.9999
GX	11	1 (9.1)	N.A. (3.12, N.A.)	14	0	N.E.	N.E. 0.1859	
G1	8	1 (12.5)	N.A. (6.54, N.A.)	8	0	N.E.	N.E. 0.3711	
G2	58	16 (27.6)	23.06 (14.55, N.A.)	50	0	N.E.	N.E. 0.0002	
G3	28	3 (10.7)	N.A. (9.66, N.A.)	36	0	N.E.	N.E. 0.0575	
NOT OTHERWISE SPECIFIED	51	12 (23.5)	19.12 (19.12, N.A.)	37	0	N.E.	N.E. 0.0023	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

Protocol: CA209648 Page 6 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
LOCATION AT INITIAL DIAGNOSIS								>0.9999
UPPER THORACIC	37	7 (18.9)	N.A. (23.06, N.A.)	25	0	N.E.	N.E. 0.0479	
MIDDLE THORACIC	50	16 (32.0)	N.A. (3.84, N.A.)	52	0	N.E.	N.E. <0.0001	
LOWER THORACIC	59	6 (10.2)	N.A.	60	0	N.E.	N.E. 0.0135	
GASTROESOPHAGEAL JUNCTION	11	3 (27.3)	14.55 (9.66, N.A.)	8	0	N.E.	N.E. N.A.	
DISEASE STATUS AT CURRENT DIAGNOSIS								>0.9999
RECURRENT - LOCO-REGIONAL	8	2 (25.0)	19.12 (0.72, N.A.)	13	0	N.E.	N.E. 0.1698	
RECURRENT - DISTANT	25	5 (20.0)	N.A. (6.87, N.A.)	27	0	N.E.	N.E. 0.0203	
DE NOVO METASTATIC	107	21 (19.6)	N.A. (23.06, N.A.)	81	0	N.E.	N.E. <0.0001	
UNRESECTABLE ADVANCED	18	5 (27.8)	14.55 (8.41, N.A.)	24	0	N.E.	N.E. 0.0320	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

Protocol: CA209648 Page 7 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
SMOKING STATUS								0.9997
CURRENT/FORMER	136	31 (22.8)	N.A. (19.12, N.A.)	111	0	N.E.	N.E. <0.0001	
NEVER/UNKNOWN	22	2 (9.1)	N.A.	34	0	N.E.	N.E. 0.0652	
ALCOHOL USE								0.9998
CURRENT/FORMER	126	29 (23.0)	N.A. (23.06, N.A.)	117	0	N.E.	N.E. <0.0001	
NEVER/UNKNOWN	32	4 (12.5)	N.A. (14.55, N.A.)	28	0	N.E.	N.E. 0.0953	
NUMBER OF ORGANS WITH METASTASES AT BASELINE (PER IRT)								0.9996
<= 1	80	27 (33.8)	19.12 (9.66, N.A.)	69	0	N.E.	N.E. <0.0001	
>= 2	78	6 (7.7)	N.A.	76	0	N.E.	N.E. 0.0130	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

Protocol: CA209648 Page 8 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TIME FROM INITIAL DISEASE DIAGNOSIS TO RANDOMIZATION								0.9998
< 1 YEAR	128	27 (21.1)	N.A. (23.06, N.A.)	115	0	N.E.	N.E. <0.0001	
1 - < 3 YEARS	25	3 (12.0)	N.A. (6.87, N.A.)	21	0	N.E.	N.E. 0.1000	
PRIOR SURGERY (EXCLUDING BIOPSY)								0.9999
YES	38	7 (18.4)	N.A. (19.12, N.A.)	37	0	N.E.	N.E. 0.0194	
NO	120	26 (21.7)	N.A. (23.06, N.A.)	108	0	N.E.	N.E. <0.0001	
PRIOR RADIOTHERAPY								>0.9999
YES	26	6 (23.1)	N.A. (6.87, N.A.)	27	0	N.E.	N.E. 0.0176	
NO	132	27 (20.5)	N.A. (23.06, N.A.)	118	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

Protocol: CA209648 Page 9 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1 CPS I								>0.9999
< 10	53	12 (22.6)	N.A. (8.41, N.A.)	54	0	N.E.	N.E. 0.0009	
>= 10	92	18 (19.6)	N.A. (23.06, N.A.)	89	0	N.E.	N.E. <0.0001	
PD-L1 CPS II								0.9998
< 5	29	3 (10.3)	N.A. (6.54, N.A.)	24	0	N.E.	N.E. 0.1370	
>= 5	116	27 (23.3)	N.A. (19.12, N.A.)	119	0	N.E.	N.E. <0.0001	
TUMOR CELL PD-L1 EXPRESSION I (PER CRF)								>0.9999
< 10%	55	11 (20.0)	N.A.	57	0	N.E.	N.E. 0.0009	
>= 10%	103	22 (21.4)	N.A. (19.12, N.A.)	88	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

Protocol: CA209648 Page 10 of 10

Serious Immune-mediated Adverse Events: Subgroup Time-Adjusted Analyses
Any imAEs
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

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

Serious Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI)(mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI)(mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) P-value (2)(3)	Test for Interaction P-value (4)(5)
TUMOR CELL PD-L1 EXPRESSION II (PER CRF)								0.9998
< 5%	38	6 (15.8)	N.A. (8.41, N.A.)	41	0	N.E.	N.E. 0.0131	
>= 5%	120	27 (22.5)	N.A. (19.12, N.A.)	104	0	N.E.	N.E. <0.0001	

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.M.E. = Not meaningful estimate; N.E. = Not estimable.
(1) KME of median time to first AE. (2) Unstratified log-rank test.
(3) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(4) 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: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimae2-ebr503.sas 05MAR2022:08:49:07

4.3.3 Zusatzanalysen: Weitere UE von besonderem Interesse (OESI)

4.3.3.1 Zeit bis zum ersten Auftreten von jeglichen OESI

Protocol: CA209648 Page 1 of 2

Other Events of Special Interest: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH ANY OESIS	158	6 (3.8)	N.A.	145	0	N.E.	N.E.	0.0657
SUBJECTS WITH DEMYELINATION EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	158	1 (0.6)	N.A.	145	0	N.E.	N.E.	0.3482
SUBJECTS WITH MYASTHENIC SYNDROME	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOSITIS/ RHABDOMYOLYSIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.2881

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2).
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr503.sas 08FEB2022:09:42:22

Protocol: CA209648 Page 2 of 2

Other Events of Special Interest: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH UVEITIS EVENT	158	2 (1.3)	N.A.	145	0	N.E.	N.E.	0.2382

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2).
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr503.sas 08FEB2022:09:42:22

4.3.3.2 Zeit bis zum ersten Auftreten von schweren OESI (CTCAE Grad ≥ 3)

Protocol: CA209648 Page 1 of 2

Other Events of Special Interest with CTCAE Grade 3-4-5: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

	Nivo + Ipi			Chemotherapy			Nivo + Ipi vs. Chemotherapy	
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	158	4 (2.5)	N.A.	145	0	N.E.	N.E.	0.2128
SUBJECTS WITH DEMYELINATION EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYASTHENIC SYNDROME	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOSITIS/ RHABDOMYOLYSIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.2881

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2).
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr503.sas 08FEB2022:09:42:36

Protocol: CA209648 Page 2 of 2

Other Events of Special Interest with CTCAE Grade 3-4-5: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH UVEITIS EVENT	158	1 (0.6)	N.A.	145	0	N.E.	N.E.	0.5127

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2).
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr503.sas 08FEB2022:09:42:36

4.3.3.3 Zeit bis zum ersten Auftreten von schwerwiegenden OESI

Protocol: CA209648 Page 1 of 2

Serious Other Events of Special Interest: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH ANY OESIS	158	5 (3.2)	N.A.	145	0	N.E.	N.E.	0.1127
SUBJECTS WITH DEMYELINATION EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYASTHENIC SYNDROME	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOSITIS/ RHABDOMYOLYSIS EVENT	158	0	N.E.	145	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	158	3 (1.9)	N.A.	145	0	N.E.	N.E.	0.2881

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2).
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr503.sas 08FEB2022:09:42:49

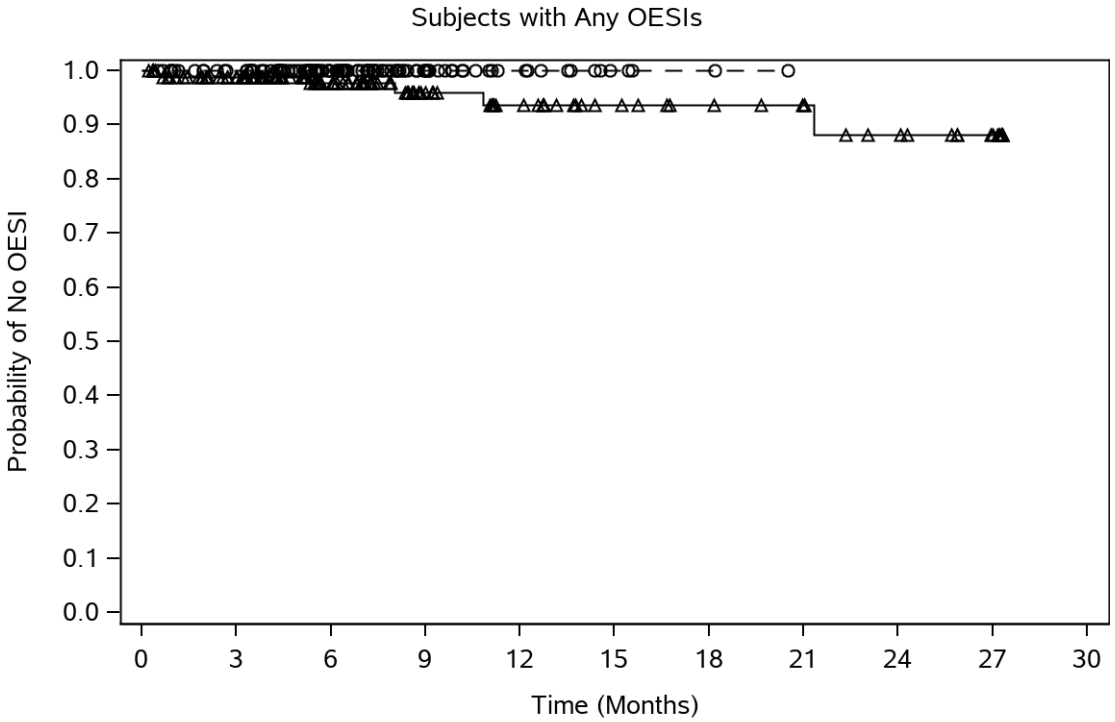
Protocol: CA209648 Page 2 of 2

Serious Other Events of Special Interest: Time-Adjusted Analyses
All Treated Subjects, Nivo+Ipi vs Chemo, with Tumor Cell PD-L1 >=1% per IRT

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi KME (95%CI) (mon) (1)	Chemotherapy N	Chemotherapy Subjects with Event n (%)	Chemotherapy KME (95%CI) (mon) (1)	Nivo + Ipi vs. Chemotherapy HR (95%CI) (2)	Nivo + Ipi vs. Chemotherapy P-value (3)
SUBJECTS WITH UVEITIS EVENT	158	2 (1.3)	N.A.	145	0	N.E.	N.E.	0.2382

Oct 2021 DBL. Includes events reported between first dose and 100 days after last dose of the study therapy.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo.
(3) Stratified Log-rank test
stratified by ECOG PS (0/1), # of organs with metastases (<=1/>=2).
MedDRA Version: 24.0; CTC Version 4.0
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-oesitahrt-ebr503.sas 08FEB2022:09:42:49

4.3.3.4 KM-Kurven – Zeit bis zum ersten Auftreten von jeglichen OESI



Number of Subjects at Risk

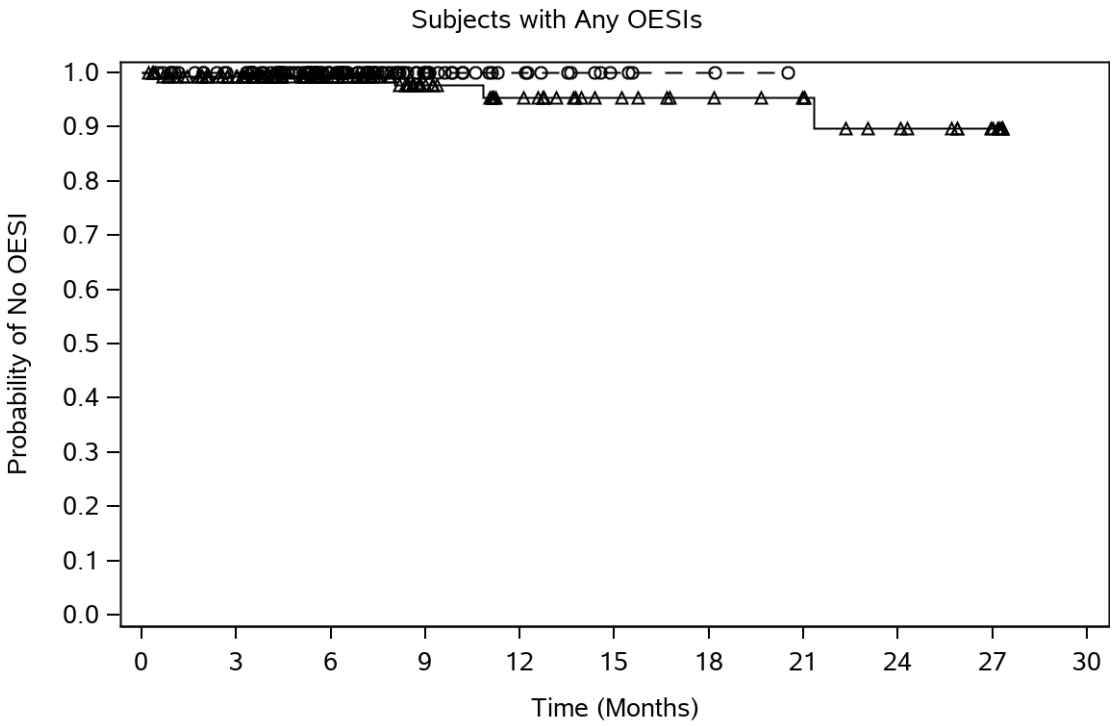
Nivo + Ipi	158	133	81	46	36	26	22	19	14	8	0
Chemo	145	132	68	27	12	4	2	0	0	0	0

—△— Nivo + Ipi (events: 6/158), median and 95% CI: N.A.

—○— Chemo (events: 0/145), median and 95% CI: N.E.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: N.E., p-value: 0.0657

4.3.3.5 KM-Kurven – Zeit bis zum ersten Auftreten von schweren OESI (CTCAE Grad ≥ 3)



Number of Subjects at Risk

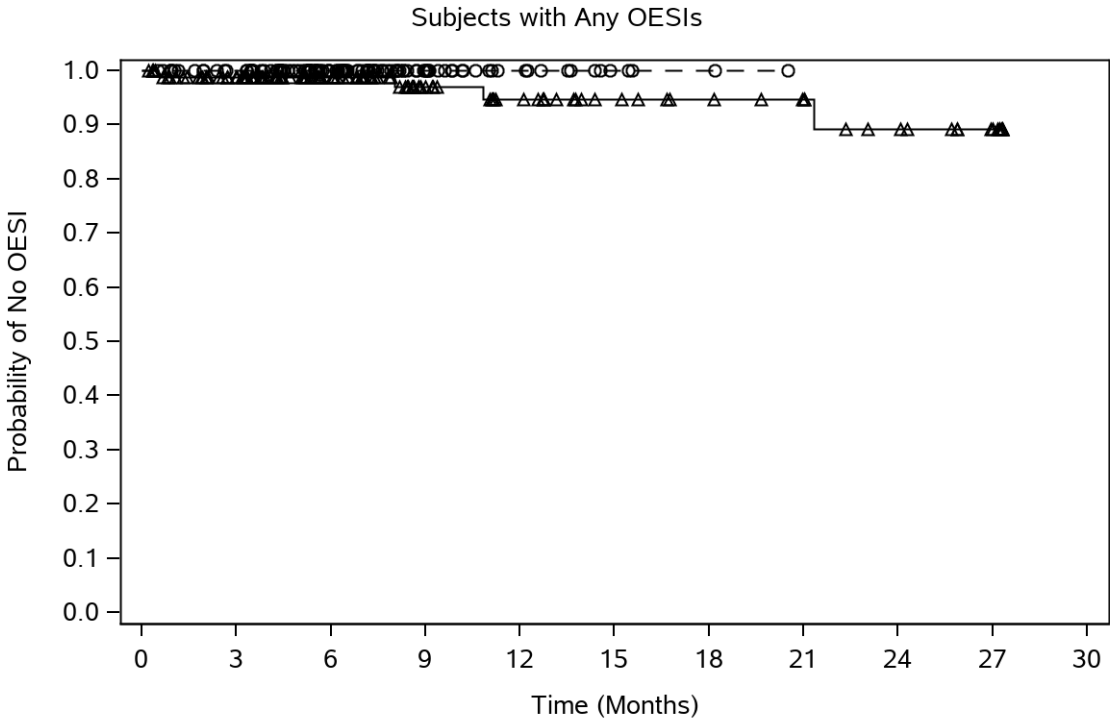
Nivo + Ipi	158	134	82	46	36	26	22	19	14	8	0
Chemo	145	132	68	27	12	4	2	0	0	0	0

Nivo + Ipi (events: 4/158), median and 95% CI: N.A.

Chemo (events: 0/145), median and 95% CI: N.E.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: N.E., p-value: 0.2128

4.3.3.6 KM-Kurven – Zeit bis zum ersten Auftreten von schwerwiegenden OESI



Number of Subjects at Risk

Nivo + Ipi	158	133	82	46	36	26	22	19	14	8	0
Chemo	145	132	68	27	12	4	2	0	0	0	0

Nivo + Ipi (events: 5/158), median and 95% CI: N.A.

Chemo (events: 0/145), median and 95% CI: N.E.

Hazard Ratio (Nivo + Ipi vs. Chemo) and 95% CI: N.E., p-value: 0.1127