Dossier zur Nutzenbewertung gemäß § 35a SGB V

Nivolumab (OPDIVO®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 N

Anhang 4-G

Erstlinientherapie des nicht-resezierbaren malignen Pleuramesothelioms bei Erwachsenen

Ergänzende Analysen

Stand: 29.06.2021

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Anhang 4-G: Ergänzende Analysen der RCT CA209-743

Anhang 4-G 1: Endpunkte Morbidität und Lebensqualität: Zeit bis zur dauerhaften Verschlechterung

Anhang 4-G 1.1: Zeit bis zur dauerhaften Verschlechterung um 15 mm für Endpunkt EQ-5D-VAS aus CA209-743

Responderanalyse Zeit bis zur dauerhaften Verschlechterung um 15 mm des Endpunktes Gesundheitszustand gemäß EQ-5D-VAS aus CA209-743.

	Nivolumab + Ipilimumab				**Chemotherapie**				**Nivolumab + Ipilimumab vs. Chemotherapie**	
EQ-5D (15 mm)	**N[(1)]**	**Patienten mit Ereignis n (%)**	**Zensierte Patienten n (%)**	**Mediane Zeit bis zur Verschlechterung in Monaten (95 %-KI)[(2)]**	**N[(1)]**	**Patienten mit Ereignis n (%)**	**Zensierte Patienten n (%)**	**Mediane Zeit bis zur Verschlechterung in Monaten (95 %-KI)[(2)]**	**HR (95 %-KI) p-Wert[(3)]**	**AD in Monaten**
EQ-5D-VAS (15 mm)	303	81 (26,7%)	222 (73,3%)	26,15 (22,64; N,A,)	302	99 (32,8%)	203 (67,2%)	16,69 (15,01; 21,75)	0,653 (0,486; 0,879) 0,0049	9,46

AD = Absolute Differenz; EQ-5D = European Quality of Life Questionnaire 5 Dimensions; HR = Hazard Ratio; KI = Konfidenzintervall; N.A. = nicht anwendbar bzw. nicht erreicht; VAS = visueller Analogskalenwert

(1) Anzahl der randomisierten Patienten.

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

(3) Cox-Proportional-Hazards-Modell mit Wert zu Studienbeginn als Kovariate.

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

Table 7.1: Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Anorexia (Appetite) (MID=10)			
Event:	166/605 (27.4%)	85/303 (28.1%)	81/302 (26.8%)
Patients with a single deterioration and no data afterwards	9/166 (5.4%)	6/85 (7.1%)	3/81 (3.7%)
Patients with a single deterioration followed by death [1]	38/166 (22.9%)	19/85 (22.4%)	19/81 (23.5%)
Patients with deterioration events occuring at 2 or more time points	119/166 (71.7%)	60/85 (70.6%)	59/81 (72.8%)
Censored:	439/605 (72.6%)	218/303 (71.9%)	221/302 (73.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	127/439 (28.9%)	77/218 (35.3%)	50/221 (22.6%)
Patients with no deterioration (censored at last PRO assessment)	312/439 (71.1%)	141/218 (64.7%)	171/221 (77.4%)
LCSS: Anorexia (Appetite) (MID=15)			
Event:	138/605 (22.8%)	70/303 (23.1%)	68/302 (22.5%)
Patients with a single deterioration and no data afterwards	8/138 (5.8%)	5/70 (7.1%)	3/68 (4.4%)
Patients with a single deterioration followed by death [1]	36/138 (26.1%)	16/70 (22.9%)	20/68 (29.4%)
Patients with deterioration events occuring at 2 or more time points	94/138 (68.1%)	49/70 (70.0%)	45/68 (66.2%)
Censored:	467/605 (77.2%)	233/303 (76.9%)	234/302 (77.5%)
Patients with deterioration and later improvement (censored last PRO assessment)	121/467 (25.9%)	71/233 (30.5%)	50/234 (21.4%)
Patients with no deterioration (censored at last PRO assessment)	346/467 (74.1%)	162/233 (69.5%)	184/234 (78.6%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
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Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Fatigue (MID=10)			
Event:	216/605 (35.7%)	104/303 (34.3%)	112/302 (37.1%)
Patients with a single deterioration and no data afterwards	4/216 (1.9%)	3/104 (2.9%)	1/112 (0.9%)
Patients with a single deterioration followed by death [1]	34/216 (15.7%)	12/104 (11.5%)	22/112 (19.6%)
Patients with deterioration events occuring at 2 or more time points	178/216 (82.4%)	89/104 (85.6%)	89/112 (79.5%)
Censored:	389/605 (64.3%)	199/303 (65.7%)	190/302 (62.9%)
Patients with deterioration and later improvement (censored last PRO assessment)	115/389 (29.6%)	79/199 (39.7%)	36/190 (18.9%)
Patients with no deterioration (censored at last PRO assessment)	274/389 (70.4%)	120/199 (60.3%)	154/190 (81.1%)
LCSS: Fatigue (MID=15)			
Event:	182/605 (30.1%)	89/303 (29.4%)	93/302 (30.8%)
Patients with a single deterioration and no data afterwards	5/182 (2.7%)	2/89 (2.2%)	3/93 (3.2%)
Patients with a single deterioration followed by death [1]	30/182 (16.5%)	11/89 (12.4%)	19/93 (20.4%)
Patients with deterioration events occuring at 2 or more time points	147/182 (80.8%)	76/89 (85.4%)	71/93 (76.3%)
Censored:	423/605 (69.9%)	214/303 (70.6%)	209/302 (69.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	109/423 (25.8%)	71/214 (33.2%)	38/209 (18.2%)
Patients with no deterioration (censored at last PRO assessment)	314/423 (74.2%)	143/214 (66.8%)	171/209 (81.8%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
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Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Cough (MID=10)			
Event:	141/605 (23.3%)	87/303 (28.7%)	54/302 (17.9%)
Patients with a single deterioration and no data afterwards	7/141 (5.0%)	5/87 (5.7%)	2/54 (3.7%)
Patients with a single deterioration followed by death [1]	41/141 (29.1%)	21/87 (24.1%)	20/54 (37.0%)
Patients with deterioration events occuring at 2 or more time points	93/141 (66.0%)	61/87 (70.1%)	32/54 (59.3%)
Censored:	464/605 (76.7%)	216/303 (71.3%)	248/302 (82.1%)
Patients with deterioration and later improvement (censored last PRO assessment)	135/464 (29.1%)	80/216 (37.0%)	55/248 (22.2%)
Patients with no deterioration (censored at last PRO assessment)	329/464 (70.9%)	136/216 (63.0%)	193/248 (77.8%)
LCSS: Cough (MID=15)			
Event:	108/605 (17.9%)	59/303 (19.5%)	49/302 (16.2%)
Patients with a single deterioration and no data afterwards	6/108 (5.6%)	2/59 (3.4%)	4/49 (8.2%)
Patients with a single deterioration followed by death [1]	36/108 (33.3%)	15/59 (25.4%)	21/49 (42.9%)
Patients with deterioration events occuring at 2 or more time points	66/108 (61.1%)	42/59 (71.2%)	24/49 (49.0%)
Censored:	497/605 (82.1%)	244/303 (80.5%)	253/302 (83.8%)
Patients with deterioration and later improvement (censored last PRO assessment)	128/497 (25.8%)	79/244 (32.4%)	49/253 (19.4%)
Patients with no deterioration (censored at last PRO assessment)	369/497 (74.2%)	165/244 (67.6%)	204/253 (80.6%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
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Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Dyspnea (MID=10)			
Event:	174/605 (28.8%)	99/303 (32.7%)	75/302 (24.8%)
Patients with a single deterioration and no data afterwards	6/174 (3.4%)	5/99 (5.1%)	1/75 (1.3%)
Patients with a single deterioration followed by death [1]	28/174 (16.1%)	13/99 (13.1%)	15/75 (20.0%)
Patients with deterioration events occuring at 2 or more time points	140/174 (80.5%)	81/99 (81.8%)	59/75 (78.7%)
Censored:	431/605 (71.2%)	204/303 (67.3%)	227/302 (75.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	118/431 (27.4%)	69/204 (33.8%)	49/227 (21.6%)
Patients with no deterioration (censored at last PRO assessment)	313/431 (72.6%)	135/204 (66.2%)	178/227 (78.4%)
LCSS: Dyspnea (MID=15)			
Event:	136/605 (22.5%)	76/303 (25.1%)	60/302 (19.9%)
Patients with a single deterioration and no data afterwards	4/136 (2.9%)	3/76 (3.9%)	1/60 (1.7%)
Patients with a single deterioration followed by death [1]	29/136 (21.3%)	10/76 (13.2%)	19/60 (31.7%)
Patients with deterioration events occuring at 2 or more time points	103/136 (75.7%)	63/76 (82.9%)	40/60 (66.7%)
Censored:	469/605 (77.5%)	227/303 (74.9%)	242/302 (80.1%)
Patients with deterioration and later improvement (censored last PRO assessment)	117/469 (24.9%)	69/227 (30.4%)	48/242 (19.8%)
Patients with no deterioration (censored at last PRO assessment)	352/469 (75.1%)	158/227 (69.6%)	194/242 (80.2%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
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Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Pain (MID=10)			
Event:	157/605 (26.0%)	85/303 (28.1%)	72/302 (23.8%)
Patients with a single deterioration and no data afterwards	7/157 (4.5%)	3/85 (3.5%)	4/72 (5.6%)
Patients with a single deterioration followed by death [1]	38/157 (24.2%)	17/85 (20.0%)	21/72 (29.2%)
Patients with deterioration events occuring at 2 or more time points	112/157 (71.3%)	65/85 (76.5%)	47/72 (65.3%)
Censored:	448/605 (74.0%)	218/303 (71.9%)	230/302 (76.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	102/448 (22.8%)	64/218 (29.4%)	38/230 (16.5%)
Patients with no deterioration (censored at last PRO assessment)	346/448 (77.2%)	154/218 (70.6%)	192/230 (83.5%)
LCSS: Pain (MID=15)			
Event:	128/605 (21.2%)	69/303 (22.8%)	59/302 (19.5%)
Patients with a single deterioration and no data afterwards	6/128 (4.7%)	2/69 (2.9%)	4/59 (6.8%)
Patients with a single deterioration followed by death [1]	45/128 (35.2%)	19/69 (27.5%)	26/59 (44.1%)
Patients with deterioration events occuring at 2 or more time points	77/128 (60.2%)	48/69 (69.6%)	29/59 (49.2%)
Censored:	477/605 (78.8%)	234/303 (77.2%)	243/302 (80.5%)
Patients with deterioration and later improvement (censored last PRO assessment)	99/477 (20.8%)	64/234 (27.4%)	35/243 (14.4%)
Patients with no deterioration (censored at last PRO assessment)	378/477 (79.2%)	170/234 (72.6%)	208/243 (85.6%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
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Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Symptom Distress (reversed) (MID=10)			
Event:	177/605 (29.3%)	86/303 (28.4%)	91/302 (30.1%)
Patients with a single deterioration and no data afterwards	5/177 (2.8%)	1/86 (1.2%)	4/91 (4.4%)
Patients with a single deterioration followed by death [1]	40/177 (22.6%)	15/86 (17.4%)	25/91 (27.5%)
Patients with deterioration events occuring at 2 or more time points	132/177 (74.6%)	70/86 (81.4%)	62/91 (68.1%)
Censored:	428/605 (70.7%)	217/303 (71.6%)	211/302 (69.9%)
Patients with deterioration and later improvement (censored last PRO assessment)	99/428 (23.1%)	55/217 (25.3%)	44/211 (20.9%)
Patients with no deterioration (censored at last PRO assessment)	329/428 (76.9%)	162/217 (74.7%)	167/211 (79.1%)
LCSS: Symptom Distress (reversed) (MID=15)			
Event:	139/605 (23.0%)	70/303 (23.1%)	69/302 (22.8%)
Patients with a single deterioration and no data afterwards	3/139 (2.2%)	1/70 (1.4%)	2/69 (2.9%)
Patients with a single deterioration followed by death [1]	33/139 (23.7%)	11/70 (15.7%)	22/69 (31.9%)
Patients with deterioration events occuring at 2 or more time points	103/139 (74.1%)	58/70 (82.9%)	45/69 (65.2%)
Censored:	466/605 (77.0%)	233/303 (76.9%)	233/302 (77.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	86/466 (18.5%)	48/233 (20.6%)	38/233 (16.3%)
Patients with no deterioration (censored at last PRO assessment)	380/466 (81.5%)	185/233 (79.4%)	195/233 (83.7%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
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Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Interference with Activity Level (reversed) (MID=10)			
Event:	178/605 (29.4%)	85/303 (28.1%)	93/302 (30.8%)
Patients with a single deterioration and no data afterwards	5/178 (2.8%)	2/85 (2.4%)	3/93 (3.2%)
Patients with a single deterioration followed by death [1]	37/178 (20.8%)	13/85 (15.3%)	24/93 (25.8%)
Patients with deterioration events occuring at 2 or more time points	136/178 (76.4%)	70/85 (82.4%)	66/93 (71.0%)
Censored:	427/605 (70.6%)	218/303 (71.9%)	209/302 (69.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	101/427 (23.7%)	56/218 (25.7%)	45/209 (21.5%)
Patients with no deterioration (censored at last PRO assessment)	326/427 (76.3%)	162/218 (74.3%)	164/209 (78.5%)
LCSS: Interference with Activity Level (reversed) (MID=15)			
Event:	147/605 (24.3%)	75/303 (24.8%)	72/302 (23.8%)
Patients with a single deterioration and no data afterwards	6/147 (4.1%)	2/75 (2.7%)	4/72 (5.6%)
Patients with a single deterioration followed by death [1]	33/147 (22.4%)	14/75 (18.7%)	19/72 (26.4%)
Patients with deterioration events occuring at 2 or more time points	108/147 (73.5%)	59/75 (78.7%)	49/72 (68.1%)
Censored:	458/605 (75.7%)	228/303 (75.2%)	230/302 (76.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	98/458 (21.4%)	51/228 (22.4%)	47/230 (20.4%)
Patients with no deterioration (censored at last PRO assessment)	360/458 (78.6%)	177/228 (77.6%)	183/230 (79.6%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -08.00- AMNOG TTDD Freq_v0_2.sas EXECUTED: June 22, 2021 at 13:27:48 by alejandro.moreno-koe

Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Global HRQoL (reversed) (MID=10)			
Event:	195/605 (32.2%)	102/303 (33.7%)	93/302 (30.8%)
Patients with a single deterioration and no data afterwards	6/195 (3.1%)	4/102 (3.9%)	2/93 (2.2%)
Patients with a single deterioration followed by death [1]	38/195 (19.5%)	21/102 (20.6%)	17/93 (18.3%)
Patients with deterioration events occuring at 2 or more time points	151/195 (77.4%)	77/102 (75.5%)	74/93 (79.6%)
Censored:	410/605 (67.8%)	201/303 (66.3%)	209/302 (69.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	105/410 (25.6%)	59/201 (29.4%)	46/209 (22.0%)
Patients with no deterioration (censored at last PRO assessment)	305/410 (74.4%)	142/201 (70.6%)	163/209 (78.0%)
LCSS: Global HRQoL (reversed) (MID=15)			
Event:	156/605 (25.8%)	80/303 (26.4%)	76/302 (25.2%)
Patients with a single deterioration and no data afterwards	7/156 (4.5%)	5/80 (6.3%)	2/76 (2.6%)
Patients with a single deterioration followed by death [1]	40/156 (25.6%)	21/80 (26.3%)	19/76 (25.0%)
Patients with deterioration events occuring at 2 or more time points	109/156 (69.9%)	54/80 (67.5%)	55/76 (72.4%)
Censored:	449/605 (74.2%)	223/303 (73.6%)	226/302 (74.8%)
Patients with deterioration and later improvement (censored last PRO assessment)	95/449 (21.2%)	55/223 (24.7%)	40/226 (17.7%)
Patients with no deterioration (censored at last PRO assessment)	354/449 (78.8%)	168/223 (75.3%)	186/226 (82.3%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -08.00- AMNOG TTDD Freq_v0_2.sas EXECUTED: June 22, 2021 at 13:27:48 by alejandro.moreno-koe

Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: ASBI (MID=10)			
Event:	163/605 (26.9%)	87/303 (28.7%)	76/302 (25.2%)
Patients with a single deterioration and no data afterwards	7/163 (4.3%)	4/87 (4.6%)	3/76 (3.9%)
Patients with a single deterioration followed by death [1]	38/163 (23.3%)	16/87 (18.4%)	22/76 (28.9%)
Patients with deterioration events occuring at 2 or more time points	118/163 (72.4%)	67/87 (77.0%)	51/76 (67.1%)
Censored:	442/605 (73.1%)	216/303 (71.3%)	226/302 (74.8%)
Patients with deterioration and later improvement (censored last PRO assessment)	112/442 (25.3%)	69/216 (31.9%)	43/226 (19.0%)
Patients with no deterioration (censored at last PRO assessment)	330/442 (74.7%)	147/216 (68.1%)	183/226 (81.0%)
LCSS: ASBI (MID=15)			
Event:	123/605 (20.3%)	64/303 (21.1%)	59/302 (19.5%)
Patients with a single deterioration and no data afterwards	7/123 (5.7%)	4/64 (6.3%)	3/59 (5.1%)
Patients with a single deterioration followed by death [1]	34/123 (27.6%)	15/64 (23.4%)	19/59 (32.2%)
Patients with deterioration events occuring at 2 or more time points	82/123 (66.7%)	45/64 (70.3%)	37/59 (62.7%)
Censored:	482/605 (79.7%)	239/303 (78.9%)	243/302 (80.5%)
Patients with deterioration and later improvement (censored last PRO assessment)	93/482 (19.3%)	58/239 (24.3%)	35/243 (14.4%)
Patients with no deterioration (censored at last PRO assessment)	389/482 (80.7%)	181/239 (75.7%)	208/243 (85.6%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -08.00- AMNOG TTDD Freq_v0_2.sas EXECUTED: June 22, 2021 at 13:27:48 by alejandro.moreno-koe

Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
LCSS: Three-item Index (MID=30)			
Event:	168/605 (27.8%)	88/303 (29.0%)	80/302 (26.5%)
Patients with a single deterioration and no data afterwards	6/168 (3.6%)	2/88 (2.3%)	4/80 (5.0%)
Patients with a single deterioration followed by death [1]	36/168 (21.4%)	16/88 (18.2%)	20/80 (25.0%)
Patients with deterioration events occuring at 2 or more time points	126/168 (75.0%)	70/88 (79.5%)	56/80 (70.0%)
Censored:	437/605 (72.2%)	215/303 (71.0%)	222/302 (73.5%)
Patients with deterioration and later improvement (censored last PRO assessment)	116/437 (26.5%)	63/215 (29.3%)	53/222 (23.9%)
Patients with no deterioration (censored at last PRO assessment)	321/437 (73.5%)	152/215 (70.7%)	169/222 (76.1%)
LCSS: Three-item Index (MID=45)			
Event:	139/605 (23.0%)	74/303 (24.4%)	65/302 (21.5%)
Patients with a single deterioration and no data afterwards	4/139 (2.9%)	2/74 (2.7%)	2/65 (3.1%)
Patients with a single deterioration followed by death [1]	32/139 (23.0%)	12/74 (16.2%)	20/65 (30.8%)
Patients with deterioration events occuring at 2 or more time points	103/139 (74.1%)	60/74 (81.1%)	43/65 (66.2%)
Censored:	466/605 (77.0%)	229/303 (75.6%)	237/302 (78.5%)
Patients with deterioration and later improvement (censored last PRO assessment)	92/466 (19.7%)	49/229 (21.4%)	43/237 (18.1%)
Patients with no deterioration (censored at last PRO assessment)	374/466 (80.3%)	180/229 (78.6%)	194/237 (81.9%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -08.00- AMNOG TTDD Freq_v0_2.sas EXECUTED: June 22, 2021 at 13:27:48 by alejandro.moreno-koe

Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
EQ-5D-3L: VAS (MID=7)			
Event:	249/605 (41.2%)	115/303 (38.0%)	134/302 (44.4%)
Patients with a single deterioration and no data afterwards	3/249 (1.2%)	3/115 (2.6%)	0/134 (0.0%)
Patients with a single deterioration followed by death [1]	47/249 (18.9%)	18/115 (15.7%)	29/134 (21.6%)
Patients with deterioration events occuring at 2 or more time points	199/249 (79.9%)	94/115 (81.7%)	105/134 (78.4%)
Censored:	356/605 (58.8%)	188/303 (62.0%)	168/302 (55.6%)
Patients with deterioration and later improvement (censored last PRO assessment)	108/356 (30.3%)	63/188 (33.5%)	45/168 (26.8%)
Patients with no deterioration (censored at last PRO assessment)	248/356 (69.7%)	125/188 (66.5%)	123/168 (73.2%)
EQ-5D-3L: VAS (MID=10)			
Event:	237/605 (39.2%)	107/303 (35.3%)	130/302 (43.0%)
Patients with a single deterioration and no data afterwards	3/237 (1.3%)	3/107 (2.8%)	0/130 (0.0%)
Patients with a single deterioration followed by death [1]	47/237 (19.8%)	18/107 (16.8%)	29/130 (22.3%)
Patients with deterioration events occuring at 2 or more time points	187/237 (78.9%)	86/107 (80.4%)	101/130 (77.7%)
Censored:	368/605 (60.8%)	196/303 (64.7%)	172/302 (57.0%)
Patients with deterioration and later improvement (censored last PRO assessment)	106/368 (28.8%)	61/196 (31.1%)	45/172 (26.2%)
Patients with no deterioration (censored at last PRO assessment)	262/368 (71.2%)	135/196 (68.9%)	127/172 (73.8%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -08.00- AMNOG TTDD Freq_v0_2.sas EXECUTED: June 22, 2021 at 13:27:48 by alejandro.moreno-koe

Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
EQ-5D-3L: VAS (MID=15)			
Event:	180/605 (29.8%)	81/303 (26.7%)	99/302 (32.8%)
Patients with a single deterioration and no data afterwards	5/180 (2.8%)	5/81 (6.2%)	0/99 (0.0%)
Patients with a single deterioration followed by death [1]	54/180 (30.0%)	19/81 (23.5%)	35/99 (35.4%)
Patients with deterioration events occuring at 2 or more time points	121/180 (67.2%)	57/81 (70.4%)	64/99 (64.6%)
Censored:	425/605 (70.2%)	222/303 (73.3%)	203/302 (67.2%)
Patients with deterioration and later improvement (censored last PRO assessment)	98/425 (23.1%)	55/222 (24.8%)	43/203 (21.2%)
Patients with no deterioration (censored at last PRO assessment)	327/425 (76.9%)	167/222 (75.2%)	160/203 (78.8%)
EQ-5D-3L: Utility Index Score (UK) (MID=0.08)			
Event:	247/605 (40.8%)	110/303 (36.3%)	137/302 (45.4%)
Patients with a single deterioration and no data afterwards	3/247 (1.2%)	1/110 (0.9%)	2/137 (1.5%)
Patients with a single deterioration followed by death [1]	51/247 (20.6%)	23/110 (20.9%)	28/137 (20.4%)
Patients with deterioration events occuring at 2 or more time points	193/247 (78.1%)	86/110 (78.2%)	107/137 (78.1%)
Censored:	358/605 (59.2%)	193/303 (63.7%)	165/302 (54.6%)
Patients with deterioration and later improvement (censored last PRO assessment)	95/358 (26.5%)	67/193 (34.7%)	28/165 (17.0%)
Patients with no deterioration (censored at last PRO assessment)	263/358 (73.5%)	126/193 (65.3%)	137/165 (83.0%)

NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -08.00- AMNOG TTDD Freq_v0_2.sas EXECUTED: June 22, 2021 at 13:27:48 by alejandro.moreno-koe

Table 7.1 (CONT.): Time to Definitive Deterioration Event/Censored Types (Randomized Population) (N=605)

Domains	Overall	Nivolumab plus Ipilimumab	Pemetrexed plus Cisplatin or Carboplatin
EQ-5D-3L: Utility Index Score (UK) (MID=0.15)			
Event:	210/605 (34.7%)	94/303 (31.0%)	116/302 (38.4%)
Patients with a single deterioration and no data afterwards	6/210 (2.9%)	2/94 (2.1%)	4/116 (3.4%)
Patients with a single deterioration followed by death [1]	54/210 (25.7%)	23/94 (24.5%)	31/116 (26.7%)
Patients with deterioration events occuring at 2 or more time points	150/210 (71.4%)	69/94 (73.4%)	81/116 (69.8%)
Censored:	395/605 (65.3%)	209/303 (69.0%)	186/302 (61.6%)
Patients with deterioration and later improvement (censored last PRO assessment)	76/395 (19.2%)	52/209 (24.9%)	24/186 (12.9%)
Patients with no deterioration (censored at last PRO assessment)	319/395 (80.8%)	157/209 (75.1%)	162/186 (87.1%)
EQ-5D-3L: Utility Index Score (UK) (MID=0.2391)			
Event:	149/605 (24.6%)	69/303 (22.8%)	80/302 (26.5%)
Patients with a single deterioration and no data afterwards	7/149 (4.7%)	4/69 (5.8%)	3/80 (3.8%)
Patients with a single deterioration followed by death [1]	54/149 (36.2%)	28/69 (40.6%)	26/80 (32.5%)
Patients with deterioration events occuring at 2 or more time points	88/149 (59.1%)	37/69 (53.6%)	51/80 (63.8%)
Censored:	456/605 (75.4%)	234/303 (77.2%)	222/302 (73.5%)
Patients with deterioration and later improvement (censored last PRO assessment)	71/456 (15.6%)	47/234 (20.1%)	24/222 (10.8%)
Patients with no deterioration (censored at last PRO assessment)	385/456 (84.4%)	187/234 (79.9%)	198/222 (89.2%)

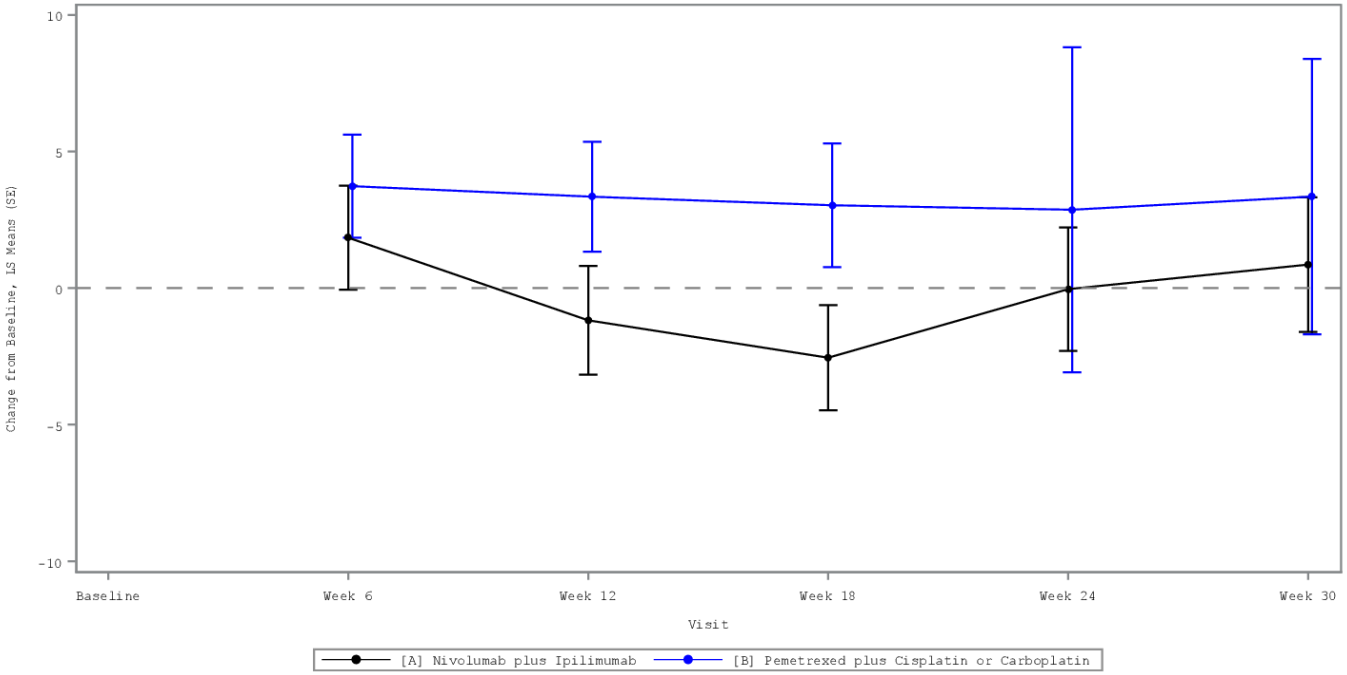
NOTE: Time to Definitive Deterioriation is the time from randomization to definitive deterioration, defined by a worsening of the respective MID without any further improvement afterwards or only missing data after deterioration.
[1] Death was defined using non-missing DTHDT dates.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -08.00- AMNOG TTDD Freq_v0_2.sas EXECUTED: June 22, 2021 at 13:27:48 by alejandro.moreno-koe

Anhang 4-G 2: Endpunkte Morbidität und Lebensqualität: Sensitivitätsanalysen (MMRM)

Anhang 4-G 2.1: Sensitivitätsanalysen zum zeitlichen Verlauf (MMRM) aus CA209-743

Sensitivitätsanalyse: Zeitlicher Verlauf der Änderung zu Studienbeginn der Endpunkte Appetitlosigkeit, Fatigue, Husten, Dyspnoe, Schmerz, Symptombelastung, Aktivitätsbeeinträchtigung, allgemeine gesundheitsbezogene Lebensqualität, Index-Wert der krankheitsbedingten Symptome, Index-Wert der gesundheitsbezogenen Lebensqualität gemäß LCSS-Meso sowie Gesundheitszustand gemäß EQ-5D-VAS aus CA209-743.

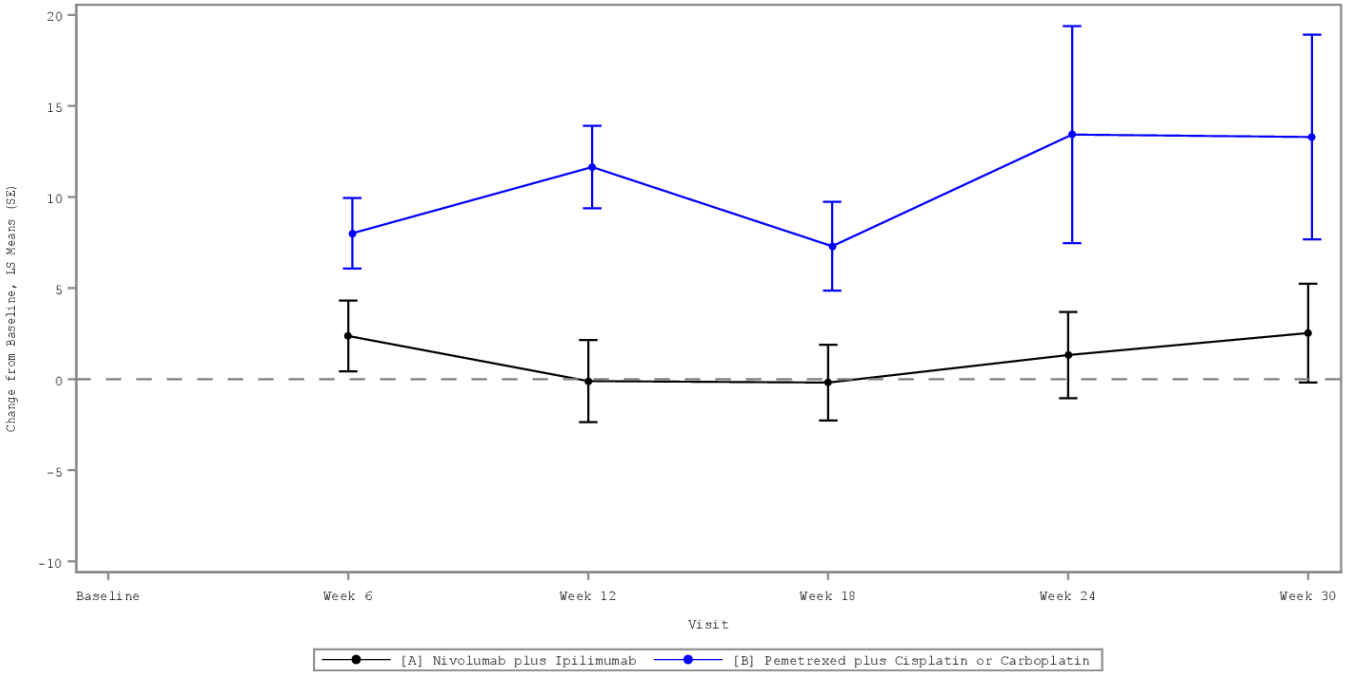
Figure 1.1.1: LCSS: Anorexia (Appetite) (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	151	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Negative difference favors Nivolumab plus Ipilimumab while a positive difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:27 by alejandro.moreno-koe

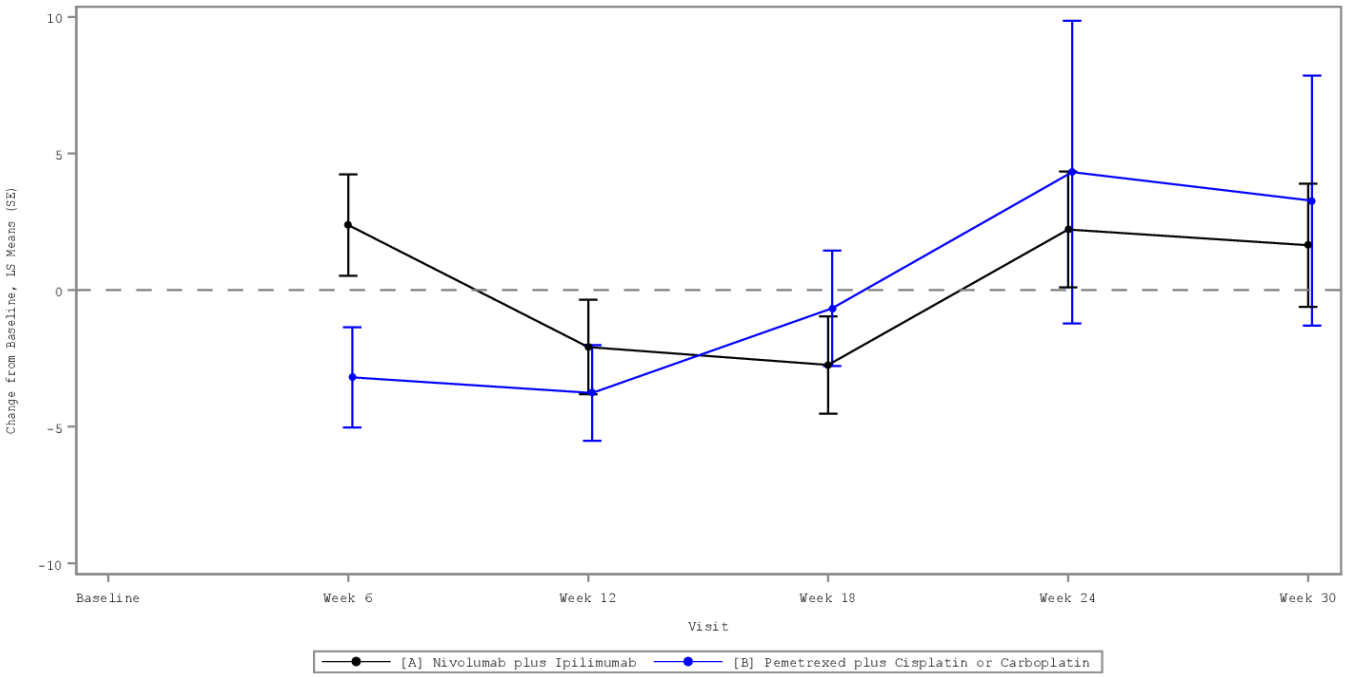
Figure 1.1.2: LCSS: Fatigue (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	151	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Negative difference favors Nivolumab plus Ipilimumab while a positive difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:29 by alejandro.moreno-koe

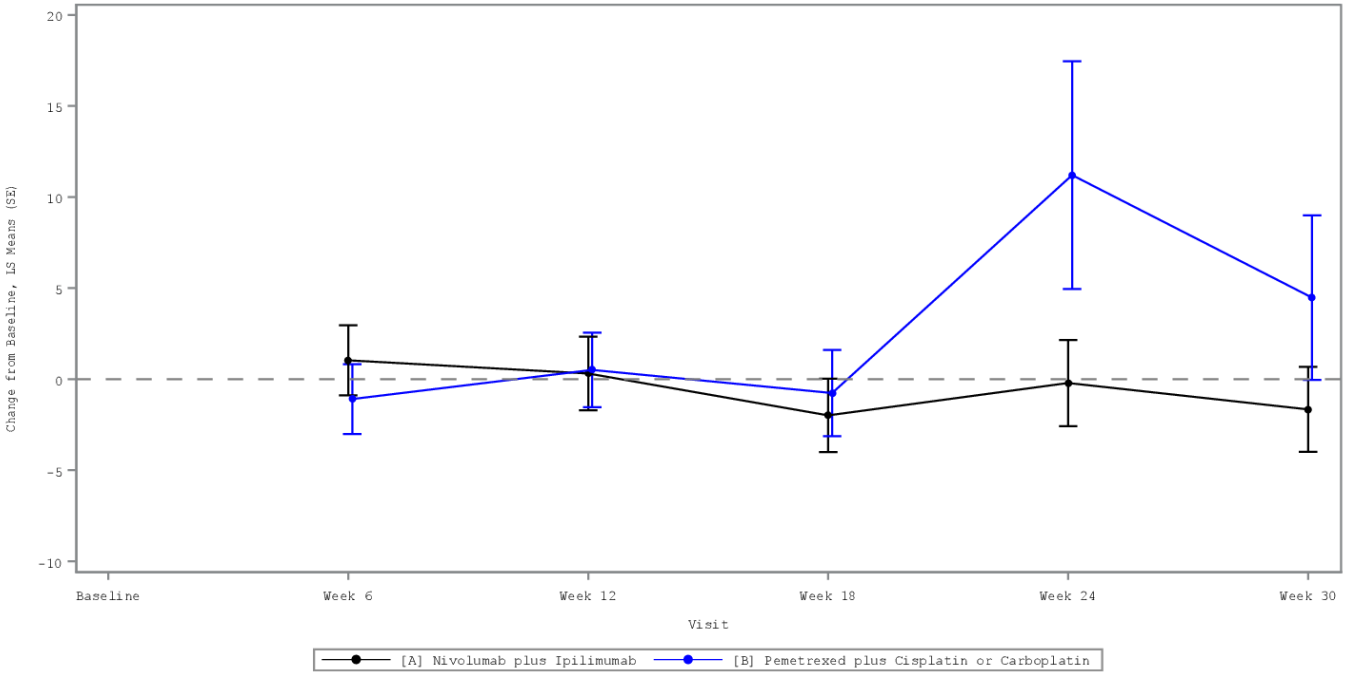
Figure 1.1.3: LCSS: Cough (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	151	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Negative difference favors Nivolumab plus Ipilimumab while a positive difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:29 by alejandro.moreno-koe

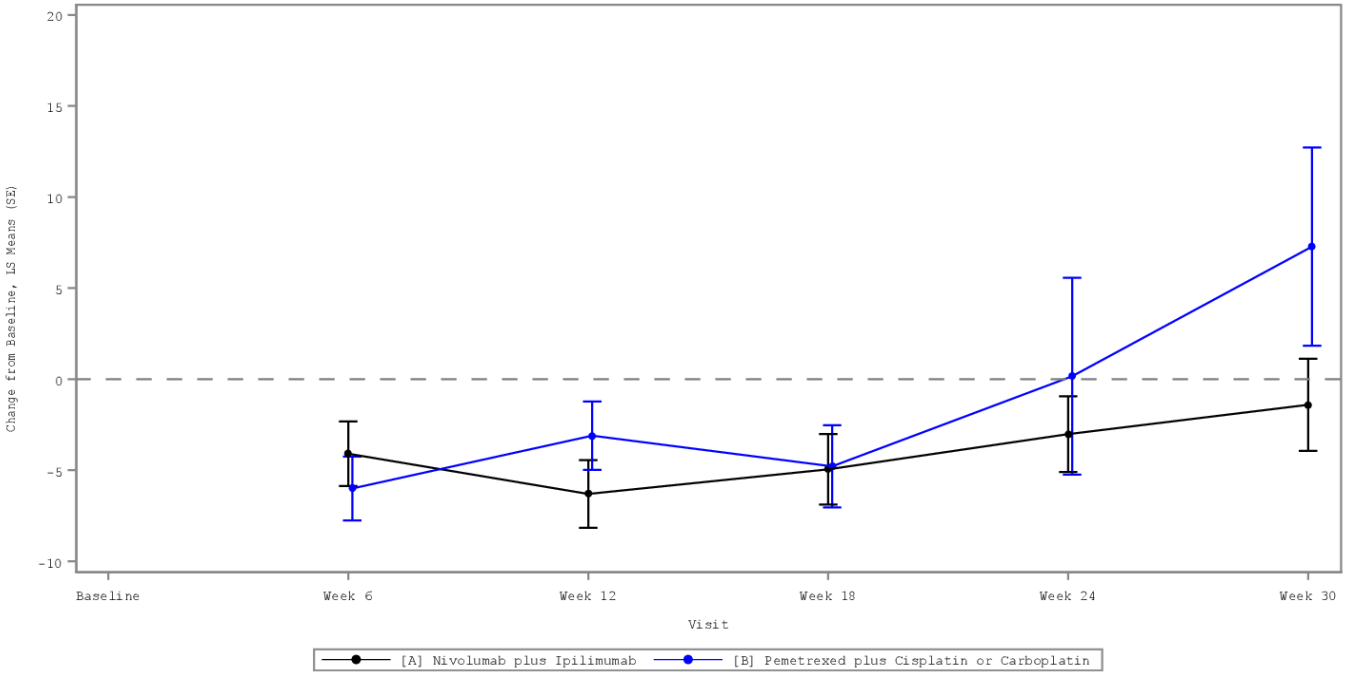
Figure 1.1.4: LCSS: Dyspnea (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	151	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Negative difference favors Nivolumab plus Ipilimumab while a positive difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:29 by alejandro.moreno-koe

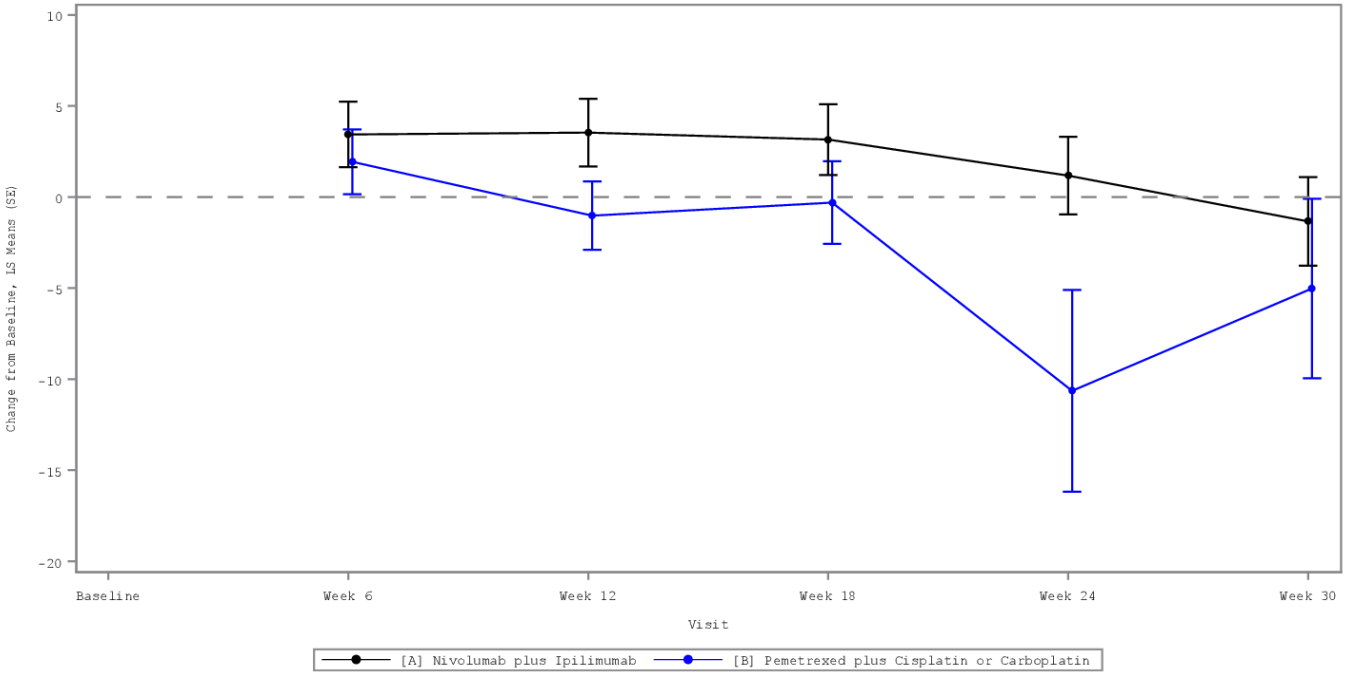
Figure 1.1.5: LCSS: Pain (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	151	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Negative difference favors Nivolumab plus Ipilimumab while a positive difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:30 by alejandro.moreno-koe

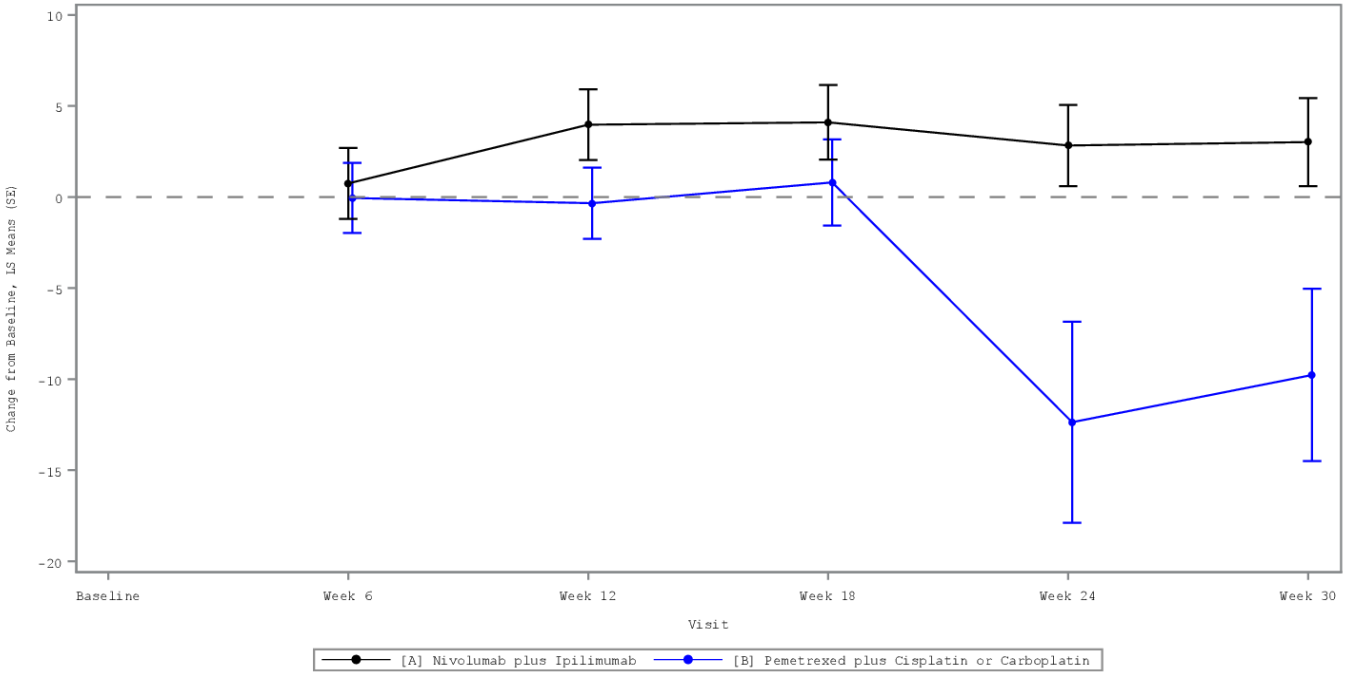
Figure 1.1.6: LCSS: Symptom Distress (reversed) (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	187	171	148	130	107
[B] Pemetrexed plus Cisplatin or Carboplatin	197	176	85	11	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Positive difference favors Nivolumab plus Ipilimumab while a negative difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:30 by alejandro.moreno-koe

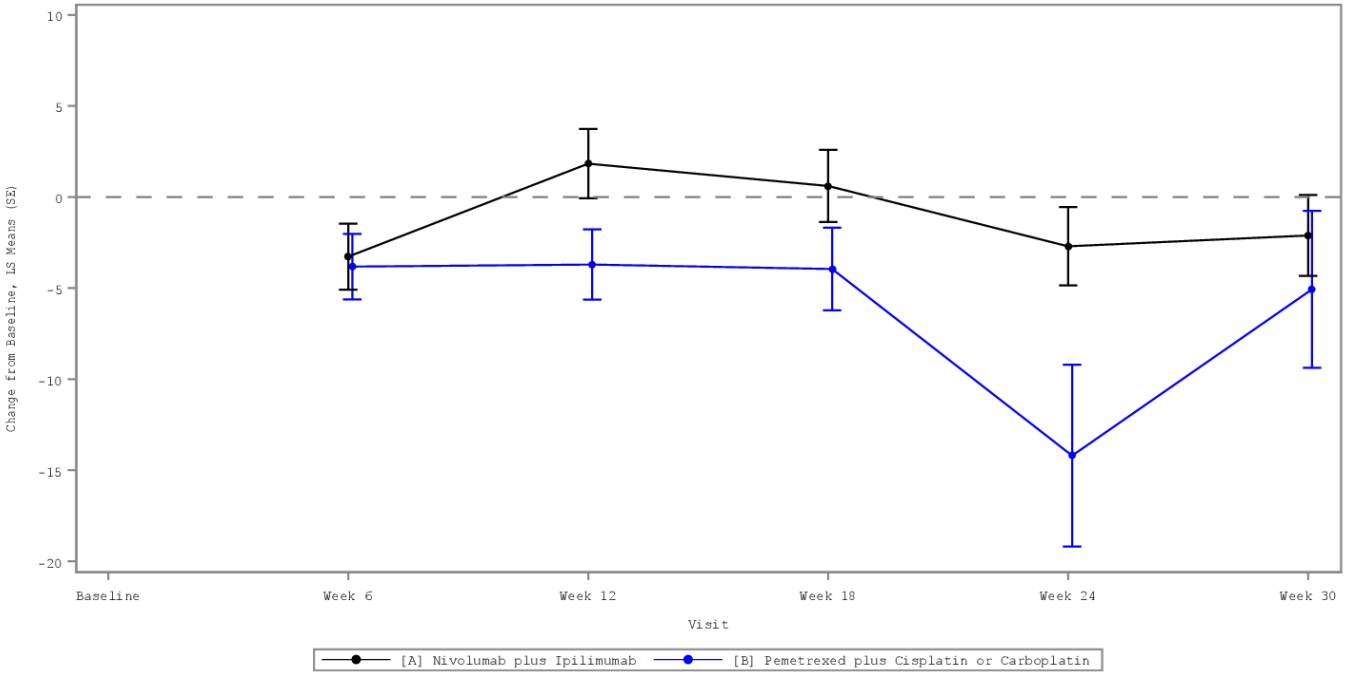
Figure 1.1.7: LCSS: Interference with Activity Level (reversed) (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	188	173	150	130	107
[B] Pemetrexed plus Cisplatin or Carboplatin	198	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Positive difference favors Nivolumab plus Ipilimumab while a negative difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:30 by alejandro.moreno-koe

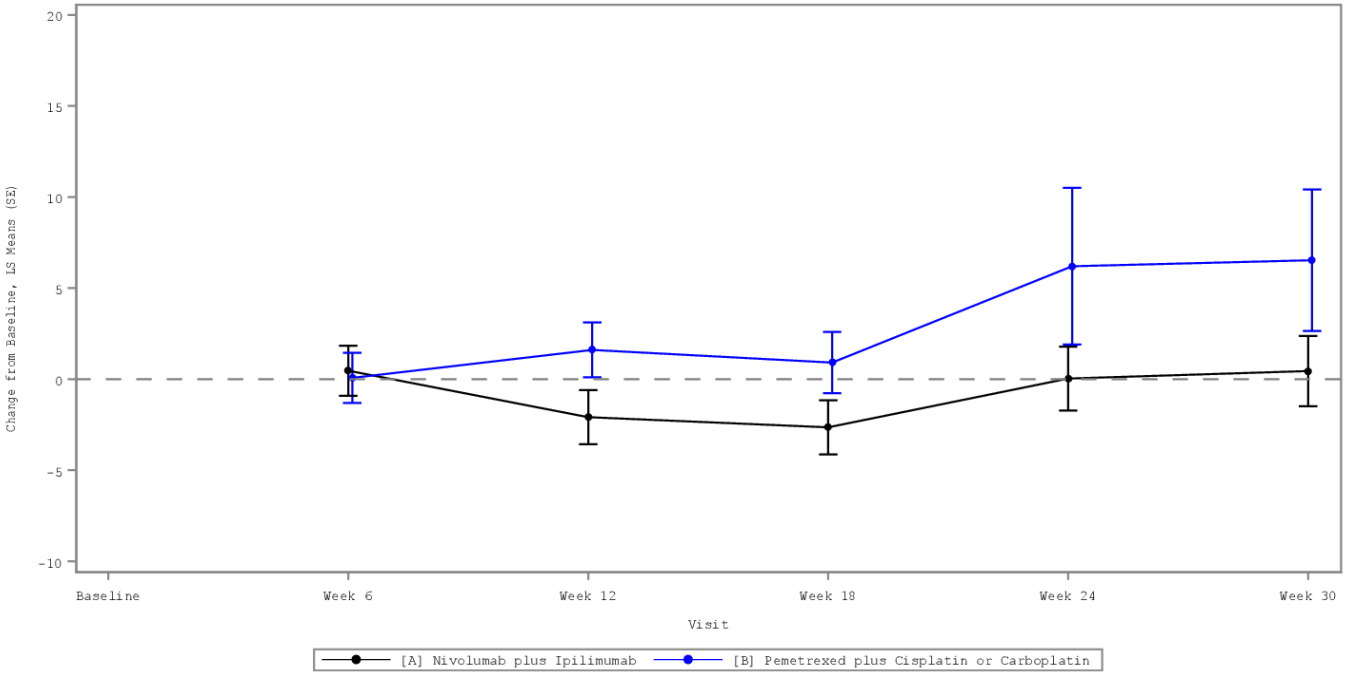
Figure 1.1.8: LCSS: Global HRQoL (reversed) (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	149	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	177	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Positive difference favors Nivolumab plus Ipilimumab while a negative difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:31 by alejandro.moreno-koe

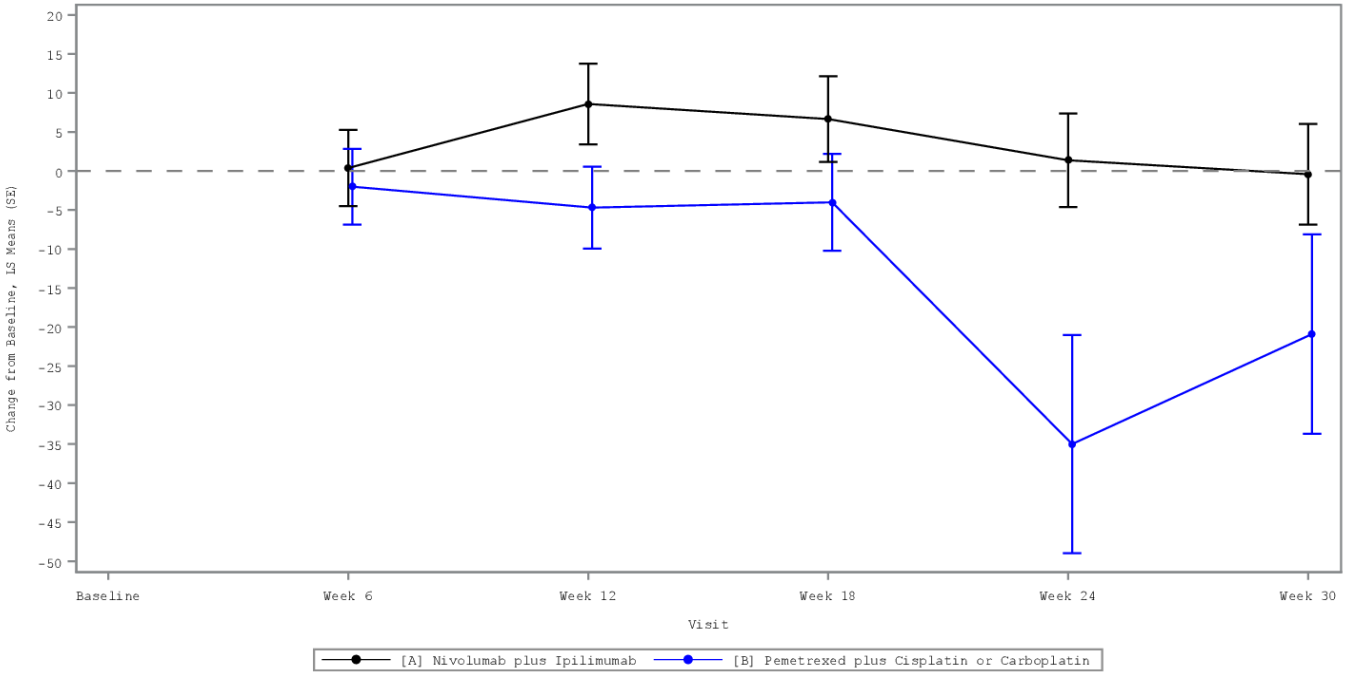
Figure 1.1.9: LCSS: ASBI (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	151	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Negative difference favors Nivolumab plus Ipilimumab while a positive difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:31 by alejandro.moreno-koe

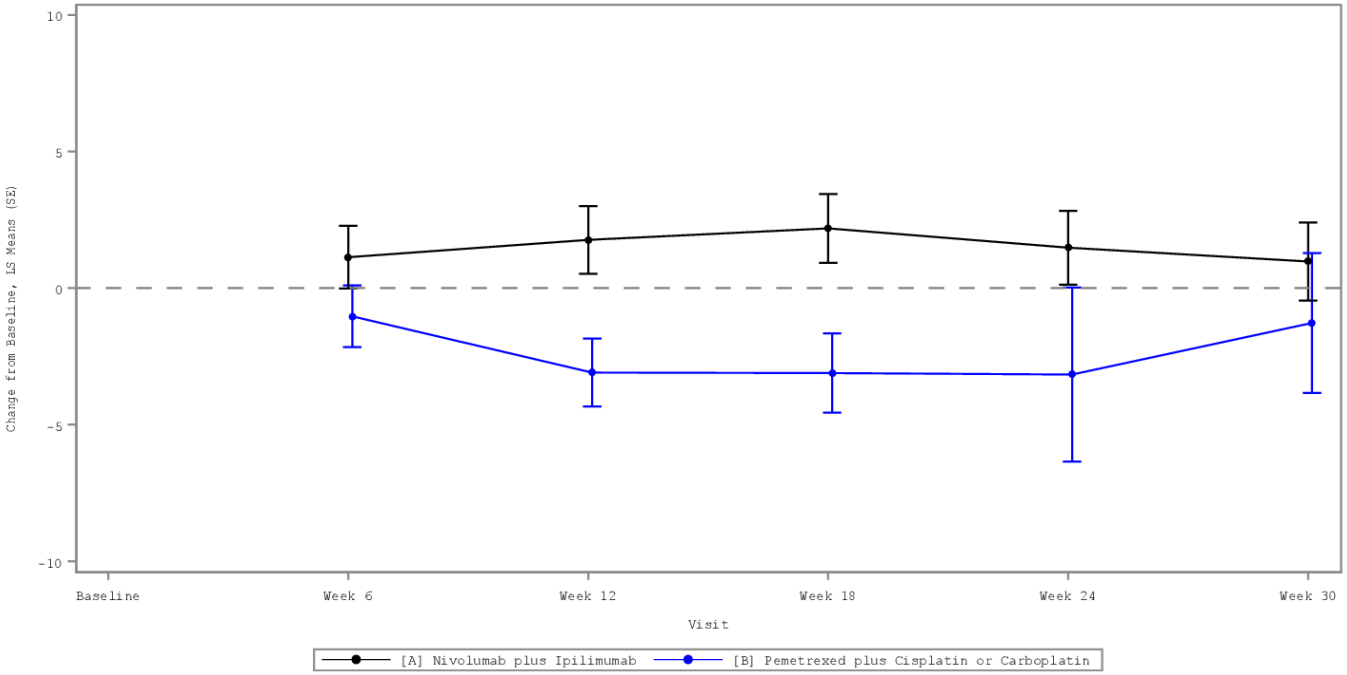
Figure 1.1.10: LCSS: Three-item Index (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	189	174	151	131	108
[B] Pemetrexed plus Cisplatin or Carboplatin	199	178	86	12	21

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Positive difference favors Nivolumab plus Ipilimumab while a negative difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:31 by alejandro.moreno-koe

Figure 1.1.16: EQ-5D-3L: VAS (Randomized PRO Population) (N=526)



[A] Nivolumab plus Ipilimumab	194	179	159	137	111
[B] Pemetrexed plus Cisplatin or Carboplatin	215	189	95	13	25

Only timepoints with 10 patients or more in both treatment groups are used in the analysis.
Estimates are based on an MMRM, treating change from baseline as the primary dependent variable, treatment and treatment*visit week interaction as fixed effects, baseline PRO score as a covariate, and visit week as a repeated measure. Models were run using a UN covariance matrix, if the model failed to converge, CS and then AR(1) were used, respectively.
Positive difference favors Nivolumab plus Ipilimumab while a negative difference favors Pemetrexed plus Cisplatin or Carboplatin.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -05.00- AMNOG MMRM Figures_v0_5.sas EXECUTED: May 14, 2021 at 13:37:33 by alejandro.moreno-koe

Anhang 4-G 2.2: Sensitivitätsanalyse mit MMRM für Endpunkte gemäß LCSS-Meso aus CA209-743

Sensitivitätsanalyse: Änderung zu Studienbeginn (MMRM) der Endpunkte Appetitlosigkeit, Fatigue, Husten, Dyspnoe, Schmerz, Indexwert der krankheitsbedingten Symptome, Symptombelastung, Aktivitätsbeeinträchtigung, allgemeine gesundheitsbezogene Lebensqualität und Index-Wert der gesundheitsbezogenen Lebensqualität gemäß LCSS-Meso aus CA209-743.

	Nivolumab + Ipilimumab			**Chemotherapie**			**Nivolumab + Ipilimumab vs. Chemotherapie**	
LCSS-Meso	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)[1]**	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)[1]**	**Mittlere Differenz (95 %-KI) p-Wert[1]**	**SMD als Hedges' g (95 %-KI)**
Appetitlosigkeit[2]	218	29,42 (27,66)	-0,21 (1,71)	216	28,01 (28,94)	3,26 (2,27)	-3,48 (-8,37; 1,41) 0,1626	-0,13 (-0,32; 0,05)
Fatigue[2]	218	36,00 (26,85)	1,18 (1,84)	216	33,73 (30,16)	10,73 (2,41)	-9,55 (-14,75; -4,36) 0,0003	-0,35 (-0,53; -0,16)
Husten[2]	218	20,78 (26,43)	0,28 (1,54)	216	21,60 (27,23)	-0,01 (2,08)	0,29 (-4,14; 4,72) 0,8976	0,01 (-0,18; 0,20)
Dyspnoe[2]	218	30,61 (28,15)	-0,51 (1,75)	216	33,43 (31,58)	2,86 (2,31)	-3,37 (-8,33; 1,59) 0,1822	-0,13 (-0,32; 0,06)
Schmerz[2]	218	28,25 (28,06)	-3,96 (1,61)	216	28,25 (29,92)	-1,30 (2,18)	-2,66 (-7,34; 2,01) 0,2628	-0,11 (-0,30; 0,08)
Index-Wert der krankheitsbedingten Symptome[2]	218	29,01 (21,32)	-0,76 (1,35)	216	29,00 (24,13)	3,06 (1,76)	-3,82 (-7,65; 0,01) 0,0507	-0,19 (-0,38; 0,00)

	Nivolumab + Ipilimumab			Chemotherapie			Nivolumab + Ipilimumab vs. Chemotherapie	
LCSS-Meso	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)(1)**	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)(1)**	**Mittlere Differenz (95 %-KI) p-Wert(1)**	**SMD als Hedges' g (95 %-KI)**

KI = Konfidenzintervall; LCSS-Meso = Lung Cancer Symptom Scale – Mesothelioma adaption; MMRM = gemischtes Modell für wiederholte Messungen; MW = Mittelwert; N = Anzahl der ausgewerteten Patienten; SD = Standardabweichung; SE = Standardfehler; SMD = standardisierte mittlere Differenz

(1) MMRM mit Änderung zu Studienbeginn als primäre abhängige Variable, Behandlung und Behandlung*Erhebungszeitpunktinteraktion als feste Effekte. Kovariaten des Modells sind Werte zu Studienbeginn. Die Erhebungszeitpunkte flossen als wiederholte Messungen ein, wobei nur Zeitpunkte mit mindestens 10 Patienten in beiden Behandlungsarmen berücksichtigt wurden. Die Modelle wurden mittels einer unstrukturierten Kovarianzmatrix berechnet. Im Falle von nicht-konvergierenden Modellen wurden zusammengesetzte Symmetrien bzw. danach autoregressive Strukturen als alternative Kovarianzstrukturen verwendet.

(2) Eine negative Änderung zu Studienbeginn bedeutet eine Verbesserung; ein negativer Effektschätzer bedeutet einen Vorteil für Nivolumab + Ipilimumab.

	Nivolumab + Ipilimumab			Chemotherapie			Nivolumab + Ipilimumab vs. Chemotherapie	
LCSS-Meso	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)[1]**	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)[1]**	**Mittlere Differenz (95 %-KI) p-Wert[1]**	**SMD als Hedges' g (95 %-KI)**
Symptom-belastung[2]	216	68,84 (27,24)	1,99 (1,67)	214	68,09 (29,14)	-3,01 (2,19)	5,01 (0,28; 9,73) 0,0379	0,20 (0,01; 0,39)
Aktivitätsbeeinträch-tigung[2]	216	63,47 (30,49)	2,93 (1,75)	216	63,59 (31,96)	-4,35 (2,24)	7,28 (2,45; 12,11) 0,0032	0,28 (0,09; 0,47)
allgemeine gesundheits-bezogene Lebens-qualität[2]	217	64,10 (27,01)	-1,13 (1,72)	216	64,27 (28,86)	-6,15 (2,14)	5,02 (0,37; 9,67) 0,0345	0,20 (0,01; 0,39)
Index-Wert der drei Lebensquali-tätsitems[2]	218	195,82 (77,25)	3,32 (4,79)	216	195,32 (82,11)	-13,32 (6,02)	16,64 (3,48; 29,79) 0,0133	0,24 (0,05; 0,43)

KI = Konfidenzintervall; LCSS-Meso = Lung Cancer Symptom Scale – Mesothelioma adaption; MMRM = gemischtes Modell für wiederholte Messungen; MW = Mittelwert; N = Anzahl der ausgewerteten Patienten; SD = Standardabweichung; SE = Standardfehler; SMD = standardisierte mittlere Differenz

(1) MMRM mit Änderung zu Studienbeginn als primäre abhängige Variable, Behandlung und Behandlung*Erhebungszeitpunktinteraktion als feste Effekte. Kovariaten des Modells sind Werte zu Studienbeginn. Die Erhebungszeitpunkte flossen als wiederholte Messungen ein, wobei nur Zeitpunkte mit mindestens 10 Patienten in beiden Behandlungsarmen berücksichtigt wurden. Die Modelle wurden mittels einer unstrukturierten Kovarianzmatrix berechnet. Im Falle von nicht-konvergierenden Modellen wurden zusammengesetzte Symmetrien bzw. danach autoregressive Strukturen als alternative Kovarianzstrukturen verwendet.

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

Anhang 4-G 2.3: Sensitivitätsanalyse mit MMRM für Endpunkt EQ-5D-VAS aus CA209-743

Sensitivitätsanalyse: Änderung zu Studienbeginn (MMRM) des Endpunktes Gesundheitszustand gemäß EQ-5D-VAS aus CA209-743.

	Nivolumab + Ipilimumab			**Chemotherapie**			**Nivolumab + Ipilimumab vs. Chemotherapie**	
EQ-5D	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)[1]**	**N**	**Werte zu Studien-beginn MW (SD)**	**Änderung zu Studienbeginn MW (SE)[1]**	**Mittlere Differenz (95 %-KI) p-Wert[1]**	**SMD als Hedges' g (95 %-KI)**
EQ-5D-VAS[2]	228	72,2 (18,9)	1,5 (1,1)	230	70,5 (18,2)	-2,3 (1,3)	3,8 (0,9; 6,8) 0,0098	0,24 (0,06; 0,43)

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

(1) MMRM mit Änderung zu Studienbeginn als primäre abhängige Variable, Behandlung und Behandlung*Erhebungszeitpunktinteraktion als feste Effekte. Kovariaten des Modells sind Werte zu Studienbeginn. Die Erhebungszeitpunkte flossen als wiederholte Messungen ein, wobei nur Zeitpunkte mit mindestens 10 Patienten in beiden Behandlungsarmen berücksichtigt wurden. Die Modelle wurden mittels einer unstrukturierten Kovarianzmatrix berechnet. Im Falle von nicht-konvergierenden Modellen wurden zusammengesetzte Symmetrien bzw. danach autoregressive Strukturen als alternative Kovarianzstrukturen verwendet.

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

Anhang 4-G 3: Endpunkte Verträglichkeit

Anhang 4-G 3.1: Ergebnisse für Endpunkte Unerwünschte Ereignisse von besonderem Interesse (AESI) aus CA209-743 – Zeit bis zum ersten Auftreten des UE

Anhang 4-G 3.1.1: Ergebnisse für Endpunkte spezifische immunvermittelte UE (imUE) aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Time-Adjusted Analyses of Immune-mediated Adverse Events on Hazard Ratio
For Patients with any imAEs
All Treated Subjects

Immune-mediated (IM) AEs	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH ANY IMAES	300	128 (42.7)	172 (57.3)	12.02 (8.90, 20.76)	284	6 (2.1)	278 (97.9)	N.A. (N.A., N.A.)	21.314 (9.361, 48.530)	<0.0001
IMAE BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH PNEUMONITIS IMAES	300	20 (6.7)	280 (93.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0002
SUBJECTS WITH DIARRHEA/COLITIS IMAES	300	26 (8.7)	274 (91.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	16.620 (2.203, 125.395)	0.0002
SUBJECTS WITH HEPATITIS IMAES	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0002
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTIONAL IMAES	300	8 (2.7)	292 (97.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0147
SUBJECTS WITH RASH IMAES	300	39 (13.0)	261 (87.0)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	9.496 (2.886, 31.244)	<0.0001

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:51:41

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Time-Adjusted Analyses of Immune-mediated Adverse Events on Hazard Ratio
For Patients with any imAEs
All Treated Subjects

Immune-mediated (IM) AEs	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH HYPERSENSITIVITY IMAES	300	5 (1.7)	295 (98.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0292
SUBJECTS WITH ENDOCRINE IMAES	300	52 (17.3)	248 (82.7)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	23.685 (5.745, 97.649)	<0.0001
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	300	7 (2.3)	293 (97.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0436
SUBJECTS WITH HYPOPHYSITIS IMAES	300	12 (4.0)	288 (96.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0014
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	300	35 (11.7)	265 (88.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	33.111 (4.525, 242.283)	<0.0001
SUBJECTS WITH HYPERTHYROIDISM IMAES	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	10.596 (1.368, 82.077)	0.0048
SUBJECTS WITH DIABETES MELLITUS IMAES	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:51:41

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Time-Adjusted Analyses of Immune-mediated Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
For Patients with imAE CTCAE grades >=3
All Treated Subjects

Immune-mediated (IM) AEs	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH IMAE CTCAE GRADES >=3	300	51 (17.0)	249 (83.0)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	37.878 (5.198, 276.028)	<0.0001
IMAE CTCAE GRADES >=3 BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH PNEUMONITIS IMAES	300	6 (2.0)	294 (98.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0163
SUBJECTS WITH DIARRHEA/COLITIS IMAES	300	12 (4.0)	288 (96.0)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	8.123 (1.015, 64.972)	0.0185
SUBJECTS WITH HEPATITIS IMAES	300	14 (4.7)	286 (95.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0018
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTIONAL IMAES	300	5 (1.7)	295 (98.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0870
SUBJECTS WITH RASH IMAES	300	8 (2.7)	292 (97.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0165

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:51:48

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Time-Adjusted Analyses of Immune-mediated Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
For Patients with imAE CTCAE grades >=3
All Treated Subjects

Immune-mediated (IM) AEs	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH HYPERSENSITIVITY IMAES	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3371
SUBJECTS WITH ENDOCRINE IMAES	300	6 (2.0)	294 (98.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0915
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH HYPOPHYSITIS IMAES	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0915
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH HYPERTHYROIDISM IMAES	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH DIABETES MELLITUS IMAES	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:51:48

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Time-Adjusted Analyses of Serious Immune-mediated Adverse Events on Hazard Ratio
For Patients with Serious imAEs
All Treated Subjects

Immune-mediated (IM) AEs	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH SERIOUS IMAE	300	44 (14.7)	256 (85.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	<0.0001
SERIOUS IMAE BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH PNEUMONITIS IMAES	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0020
SUBJECTS WITH DIARRHEA/COLITIS IMAES	300	9 (3.0)	291 (97.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0137
SUBJECTS WITH HEPATITIS IMAES	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0029
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTIONAL IMAES	300	7 (2.3)	293 (97.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0256
SUBJECTS WITH RASH IMAES	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:51:51

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Time-Adjusted Analyses of Serious Immune-mediated Adverse Events on Hazard Ratio
For Patients with Serious imAEs
All Treated Subjects

Immune-mediated (IM) AEs	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH HYPERSENSITIVITY IMAES	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3371
SUBJECTS WITH ENDOCRINE IMAES	300	9 (3.0)	291 (97.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0167
SUBJECTS WITH ADRENAL INSUFFICIENCY IMAES	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3206
SUBJECTS WITH HYPOPHYSITIS IMAES	300	5 (1.7)	295 (98.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0299
SUBJECTS WITH HYPOTHYROIDISM/ THYROIDITIS IMAES	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH HYPERTHYROIDISM IMAES	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH DIABETES MELLITUS IMAES	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:51:51

Anhang 4-G 3.1.2: Ergebnisse für Endpunkte spezifische UE (select UE) aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Time-Adjusted Analyses of Select Adverse Events on Hazard Ratio
For Patients with any Select AEs
All Treated Subjects

Select Adverse Events (AE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH ANY SLAES	300	236 (78.7)	64 (21.3)	1.48 (1.22, 1.87)	284	107 (37.7)	177 (62.3)	N.A. (N.A., N.A.)	2.783 (2.205, 3.512)	<0.0001
SLAE BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH ENDOCRINE AES	300	63 (21.0)	237 (79.0)	N.A. (N.A., N.A.)	284	8 (2.8)	276 (97.2)	N.A. (N.A., N.A.)	7.526 (3.589, 15.781)	<0.0001
SUBJECTS WITH HYPERSENSITIVITY/INFUSION REACTIONS AES	300	37 (12.3)	263 (87.7)	N.A. (N.A., N.A.)	284	7 (2.5)	277 (97.5)	N.A. (N.A., N.A.)	5.074 (2.257, 11.406)	<0.0001
SUBJECTS WITH GASTROINTESTINAL AES	300	100 (33.3)	200 (66.7)	17.61 (15.11, N.A.)	284	36 (12.7)	248 (87.3)	N.A. (N.A., N.A.)	2.090 (1.404, 3.111)	0.0002
SUBJECTS WITH HEPATIC AES	300	56 (18.7)	244 (81.3)	N.A. (N.A., N.A.)	284	11 (3.9)	273 (96.1)	N.A. (N.A., N.A.)	4.126 (2.134, 7.978)	<0.0001
SUBJECTS WITH PULMONARY AES	300	29 (9.7)	271 (90.3)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	6.670 (1.988, 22.380)	0.0004

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:50:15

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Time-Adjusted Analyses of Select Adverse Events on Hazard Ratio
For Patients with any Select AEs
All Treated Subjects

Select Adverse Events (AE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH RENAL AES	300	34 (11.3)	266 (88.7)	N.A. (N.A., N.A.)	284	28 (9.9)	256 (90.1)	N.A. (N.A., N.A.)	0.908 (0.533, 1.549)	0.7238
SUBJECTS WITH SKIN AES	300	137 (45.7)	163 (54.3)	10.78 (6.05, 23.85)	284	42 (14.8)	242 (85.2)	N.A. (N.A., N.A.)	3.102 (2.182, 4.410)	<0.0001

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:50:15

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Time-Adjusted Analyses of Select Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
For Patients with Select AE CTCAE grades >=3
All Treated Subjects

Select Adverse Events (AE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH SLAE CTCAE GRADES >=3	300	74 (24.7)	226 (75.3)	N.A. (21.68, N.A.)	284	11 (3.9)	273 (96.1)	N.A. (N.A., N.A.)	4.618 (2.403, 8.873)	<0.0001
SLAE CTCAE GRADES >=3 BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH ENDOCRINE AES	300	8 (2.7)	292 (97.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	2.885 (0.300, 27.740)	0.3366
SUBJECTS WITH HYPERSENSITIVITY/INFUSION REACTIONS AES	300	4 (1.3)	296 (98.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0489
SUBJECTS WITH GASTROINTESTINAL AES	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	2.691 (0.856, 8.457)	0.0780
SUBJECTS WITH HEPATIC AES	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0006
SUBJECTS WITH PULMONARY AES	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	4.230 (0.914, 19.582)	0.0446

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:50:23

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Time-Adjusted Analyses of Select Adverse Events with CTCAE Grade 3-4-5 on Hazard Ratio
For Patients with Select AE CTCAE grades >=3
All Treated Subjects

Select Adverse Events (AE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH RENAL AES	300	7 (2.3)	293 (97.7)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	0.992 (0.250, 3.942)	0.9912
SUBJECTS WITH SKIN AES	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	7.718 (0.965, 61.720)	0.0226

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:50:23

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Time-Adjusted Analyses of Serious Select Adverse Events on Hazard Ratio
For Patients with Serious Select AEs
All Treated Subjects

Select Adverse Events (AE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH SERIOUS SLAE	300	66 (22.0)	234 (78.0)	N.A. (N.A., N.A.)	284	7 (2.5)	277 (97.5)	N.A. (N.A., N.A.)	7.540 (3.422, 16.614)	<0.0001
SERIOUS SLAE BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH ENDOCRINE AES	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	5.759 (0.694, 47.817)	0.0663
SUBJECTS WITH HYPERSENSITIVITY/INFUSION REACTIONS AES	300	7 (2.3)	293 (97.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0179
SUBJECTS WITH GASTROINTESTINAL AES	300	16 (5.3)	284 (94.7)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	9.217 (1.169, 72.668)	0.0104
SUBJECTS WITH HEPATIC AES	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0029
SUBJECTS WITH PULMONARY AES	300	15 (5.0)	285 (95.0)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	6.669 (1.515, 29.349)	0.0037

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:50:27

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Time-Adjusted Analyses of Serious Select Adverse Events on Hazard Ratio
For Patients with Serious Select AEs
All Treated Subjects

Select Adverse Events (AE)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH RENAL AES	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	2.999 (0.812, 11.070)	0.0834
SUBJECTS WITH SKIN AES	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3263

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratified by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:50:27

Anhang 4-G 3.1.3: Ergebnisse für Endpunkte weitere UE von besonderem Interesse (OESI) aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Time-Adjusted Analyses of Other Events of Special Interest on Hazard Ratio
For Patients with any OESI
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH ANY OESIS	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	7.810 (0.979, 62.319)	0.0218
OESI BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH DEMYELINATION EVENT	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH ENCEPHALITIS EVENT	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	1.957 (0.177, 21.595)	0.5765
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH MYASTHENIC SYNDROME	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1680
SUBJECTS WITH PANCREATITIS EVENT	300	4 (1.3)	296 (98.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3157
SUBJECTS WITH UVEITIS EVENT	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3312

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratefied by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:52:56

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Time-Adjusted Analyses of Other Events of Special Interest on Hazard Ratio
For Patients with any OESI
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH MYOSITIS EVENT	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1709
SUBJECTS WITH MYOCARDITIS EVENT	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3371
SUBJECTS WITH RHABDOMYOLYSIS EVENT	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratefied by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:52:56

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Time-Adjusted Analyses of Other Events of Special Interest with CTCAE Grade 3-4-5 on Hazard Ratio
For Patients with OESI CTCAE grades >=3
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH OESI CTCAE GRADES >=3	300	8 (2.7)	292 (97.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	6.623 (0.815, 53.836)	0.0410
OESI CTCAE GRADES >=3 BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH DEMYELINATION EVENT	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH ENCEPHALITIS EVENT	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	1.892 (0.172, 20.870)	0.5964
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH MYASTHENIC SYNDROME	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1680
SUBJECTS WITH PANCREATITIS EVENT	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH UVEITIS EVENT	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3408

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratefied by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:53:03

Protocol: CA209-743 Page 2 of 2

Time-Adjusted Analyses of Other Events of Special Interest with CTCAE Grade 3-4-5 on Hazard Ratio
For Patients with OESI CTCAE grades >=3
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH MYOSITIS EVENT	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1709
SUBJECTS WITH MYOCARDITIS EVENT	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3358
SUBJECTS WITH RHABDOMYOLYSIS EVENT	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratefied by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:53:03

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Time-Adjusted Analyses of Serious Other Events of Special Interest on Hazard Ratio
For Patients with Serious OESI
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH SERIOUS OESI	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	5.787 (0.697, 48.055)	0.0654
SERIOUS OESI BY CATEGORY ACCORDING TO MEDDRA VERSION 22.1										
SUBJECTS WITH DEMYELINATION EVENT	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH ENCEPHALITIS EVENT	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	1.957 (0.177, 21.595)	0.5765
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH MYASTHENIC SYNDROME	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1680
SUBJECTS WITH PANCREATITIS EVENT	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH UVEITIS EVENT	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratefied by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:53:06

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Time-Adjusted Analyses of Serious Other Events of Special Interest on Hazard Ratio
For Patients with Serious OESI
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi N	Nivo + Ipi Subjects with Event n (%)	Nivo + Ipi Censored subjects n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Subjects with Event n (%)	Chemo Censored subjects n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
SUBJECTS WITH MYOSITIS EVENT	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.1709
SUBJECTS WITH MYOCARDITIS EVENT	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.3371
SUBJECTS WITH RHABDOMYOLYSIS EVENT	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	N.A.

April 2020 DBL. Includes events reported between first dose and 100 days after last dose of study therapy.
HR=hazard ratio; KME=Kaplan-Meier estimate. If there are no patients with events in Nivo+Ipi over Chemo, presentation of HR as n.m.e. (1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo.
(3) Log-rank Test stratefied by histology per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-slaetahr-ebr2252.sas 11DEC2020:12:53:06

Anhang 4-G 3.2: Ergebnisse für Endpunkte Unerwünschte Ereignisse auf SOC/PT-Ebene aus CA209-743

Anhang 4-G 3.2.1: Ergebnisse für Endpunkte jegliche UE auf SOC/PT-Ebene aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
TOTAL SUBJECTS WITH AN EVENT	300	299 (99.7)	1 (0.3)	0.26 (0.20, 0.39)	284	279 (98.2)	5 (1.8)	0.13 (0.10, 0.20)	0.870 (0.738, 1.026)	0.1021
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	300	212 (70.7)	88 (29.3)	2.50 (1.84, 3.88)	284	192 (67.6)	92 (32.4)	2.07 (1.48, 2.50)	0.924 (0.757, 1.128)	0.4451
FATIGUE	300	90 (30.0)	210 (70.0)	N.A. (19.65, N.A.)	284	78 (27.5)	206 (72.5)	N.A. (N.A., N.A.)	0.913 (0.667, 1.250)	0.5747
PYREXIA	300	57 (19.0)	243 (81.0)	N.A. (N.A., N.A.)	284	17 (6.0)	267 (94.0)	N.A. (N.A., N.A.)	2.810 (1.611, 4.903)	0.0001
ASTHENIA	300	52 (17.3)	248 (82.7)	N.A. (N.A., N.A.)	284	58 (20.4)	226 (79.6)	N.A. (N.A., N.A.)	0.700 (0.474, 1.033)	0.0710
OEDEMA PERIPHERAL	300	47 (15.7)	253 (84.3)	N.A. (N.A., N.A.)	284	19 (6.7)	265 (93.3)	N.A. (N.A., N.A.)	2.279 (1.328, 3.912)	0.0021
NON-CARDIAC CHEST PAIN	300	40 (13.3)	260 (86.7)	N.A. (N.A., N.A.)	284	17 (6.0)	267 (94.0)	N.A. (N.A., N.A.)	1.731 (0.954, 3.138)	0.0673

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
CHEST PAIN	300	23 (7.7)	277 (92.3)	N.A. (N.A., N.A.)	284	25 (8.8)	259 (91.2)	N.A. (N.A., N.A.)	0.690 (0.376, 1.265)	0.2273
PAIN	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	12 (4.2)	272 (95.8)	N.A. (N.A., N.A.)	1.188 (0.556, 2.538)	0.6568
CHILLS	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0012
INFLUENZA LIKE ILLNESS	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	2.724 (0.735, 10.088)	0.1182
MALAISE	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	20 (7.0)	264 (93.0)	N.A. (N.A., N.A.)	0.376 (0.167, 0.850)	0.0146
MUCOSAL INFLAMMATION	300	9 (3.0)	291 (97.0)	N.A. (N.A., N.A.)	284	15 (5.3)	269 (94.7)	N.A. (N.A., N.A.)	0.502 (0.213, 1.183)	0.1080
GASTROINTESTINAL DISORDERS	300	190 (63.3)	110 (36.7)	4.17 (3.22, 6.37)	284	191 (67.3)	93 (32.7)	0.85 (0.66, 1.38)	0.603 (0.489, 0.744)	<0.0001

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
DIARRHOEA	300	98 (32.7)	202 (67.3)	21.49 (15.11, N.A.)	284	34 (12.0)	250 (88.0)	N.A. (N.A., N.A.)	2.218 (1.479, 3.329)	<0.0001
NAUSEA	300	76 (25.3)	224 (74.7)	N.A. (N.A., N.A.)	284	124 (43.7)	160 (56.3)	N.A. (4.53, N.A.)	0.374 (0.276, 0.507)	<0.0001
CONSTIPATION	300	57 (19.0)	243 (81.0)	N.A. (N.A., N.A.)	284	86 (30.3)	198 (69.7)	N.A. (N.A., N.A.)	0.506 (0.357, 0.718)	<0.0001
VOMITING	300	48 (16.0)	252 (84.0)	N.A. (N.A., N.A.)	284	55 (19.4)	229 (80.6)	N.A. (N.A., N.A.)	0.563 (0.368, 0.861)	0.0073
ABDOMINAL PAIN	300	33 (11.0)	267 (89.0)	N.A. (N.A., N.A.)	284	13 (4.6)	271 (95.4)	N.A. (N.A., N.A.)	1.562 (0.784, 3.112)	0.2013
ABDOMINAL PAIN UPPER	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	14 (4.9)	270 (95.1)	N.A. (N.A., N.A.)	0.609 (0.263, 1.407)	0.2406
DRY MOUTH	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	2.257 (0.698, 7.293)	0.1624

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
ABDOMINAL DISTENSION	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	2.212 (0.681, 7.186)	0.1749
COLITIS	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	4.127 (0.876, 19.455)	0.0518
STOMATITIS	300	7 (2.3)	293 (97.7)	N.A. (N.A., N.A.)	284	11 (3.9)	273 (96.1)	N.A. (N.A., N.A.)	0.430 (0.149, 1.238)	0.1072
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	300	173 (57.7)	127 (42.3)	7.16 (4.40, 9.30)	284	115 (40.5)	169 (59.5)	N.A. (N.A., N.A.)	1.274 (0.996, 1.629)	0.0543
DYSPNOEA	300	80 (26.7)	220 (73.3)	N.A. (N.A., N.A.)	284	47 (16.5)	237 (83.5)	N.A. (N.A., N.A.)	1.450 (1.000, 2.104)	0.0489
COUGH	300	65 (21.7)	235 (78.3)	N.A. (N.A., N.A.)	284	25 (8.8)	259 (91.2)	N.A. (N.A., N.A.)	1.849 (1.137, 3.007)	0.0119
PLEURAL EFFUSION	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	6 (2.1)	278 (97.9)	N.A. (N.A., N.A.)	2.611 (1.021, 6.674)	0.0375

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
PNEUMONITIS	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	13.271 (1.744, 101.014)	0.0012
PRODUCTIVE COUGH	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	4.231 (1.204, 14.861)	0.0143
PULMONARY EMBOLISM	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	1.928 (0.580, 6.404)	0.2751
EPISTAXIS	300	7 (2.3)	293 (97.7)	N.A. (N.A., N.A.)	284	14 (4.9)	270 (95.1)	N.A. (N.A., N.A.)	0.336 (0.121, 0.933)	0.0278
HICCUPS	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	17 (6.0)	267 (94.0)	N.A. (N.A., N.A.)	0.108 (0.025, 0.467)	0.0003
RHINORRHOEA	300	2 (0.7)	298 (99.3)	N.A. (N.A., N.A.)	284	12 (4.2)	272 (95.8)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.)	0.0003
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	300	155 (51.7)	145 (48.3)	6.60 (4.63, 10.84)	284	67 (23.6)	217 (76.4)	N.A. (N.A., N.A.)	2.199 (1.641, 2.948)	<0.0001

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
PRURITUS	300	62 (20.7)	238 (79.3)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	10.371 (4.133, 26.027)	<0.0001
RASH	300	60 (20.0)	240 (80.0)	N.A. (N.A., N.A.)	284	21 (7.4)	263 (92.6)	N.A. (N.A., N.A.)	2.282 (1.369, 3.804)	0.0011
RASH MACULO-PAPULAR	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	2.540 (0.907, 7.116)	0.0661
DRY SKIN	300	16 (5.3)	284 (94.7)	N.A. (N.A., N.A.)	284	7 (2.5)	277 (97.5)	N.A. (N.A., N.A.)	1.838 (0.733, 4.612)	0.1877
ERYTHEMA	300	12 (4.0)	288 (96.0)	N.A. (N.A., N.A.)	284	8 (2.8)	276 (97.2)	N.A. (N.A., N.A.)	1.116 (0.439, 2.842)	0.8165
ALOPECIA	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	10 (3.5)	274 (96.5)	N.A. (N.A., N.A.)	0.180 (0.039, 0.822)	0.0127
INFECTIONS AND INFESTATIONS	300	138 (46.0)	162 (54.0)	10.02 (7.85, 15.47)	284	78 (27.5)	206 (72.5)	N.A. (N.A., N.A.)	1.455 (1.089, 1.944)	0.0108

April 2020 DBL.
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MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
PNEUMONIA	300	22 (7.3)	278 (92.7)	N.A. (N.A., N.A.)	284	9 (3.2)	275 (96.8)	N.A. (N.A., N.A.)	1.519 (0.657, 3.512)	0.3242
NASOPHARYNGITIS	300	21 (7.0)	279 (93.0)	N.A. (N.A., N.A.)	284	8 (2.8)	276 (97.2)	N.A. (N.A., N.A.)	1.380 (0.557, 3.417)	0.4848
BRONCHITIS	300	14 (4.7)	286 (95.3)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	2.451 (0.768, 7.817)	0.1174
INFLUENZA	300	14 (4.7)	286 (95.3)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	3.309 (0.910, 12.034)	0.0540
UPPER RESPIRATORY TRACT INFECTION	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	9 (3.2)	275 (96.8)	N.A. (N.A., N.A.)	0.777 (0.290, 2.081)	0.6152
LOWER RESPIRATORY TRACT INFECTION	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	2.453 (0.769, 7.827)	0.1174
URINARY TRACT INFECTION	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	1.751 (0.512, 5.988)	0.3656

April 2020 DBL.
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MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
CONJUNCTIVITIS	300	8 (2.7)	292 (97.3)	N.A. (N.A., N.A.)	284	11 (3.9)	273 (96.1)	N.A. (N.A., N.A.)	0.609 (0.236, 1.572)	0.3006
METABOLISM AND NUTRITION DISORDERS	300	125 (41.7)	175 (58.3)	16.56 (10.41, N.A.)	284	116 (40.8)	168 (59.2)	N.A. (N.A., N.A.)	0.778 (0.598, 1.013)	0.0645
DECREASED APPETITE	300	72 (24.0)	228 (76.0)	N.A. (N.A., N.A.)	284	75 (26.4)	209 (73.6)	N.A. (N.A., N.A.)	0.700 (0.498, 0.983)	0.0398
HYPONATRAEMIA	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	13 (4.6)	271 (95.4)	N.A. (N.A., N.A.)	1.027 (0.483, 2.183)	0.9456
HYPOALBUMINAEMIA	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	11 (3.9)	273 (96.1)	N.A. (N.A., N.A.)	1.517 (0.710, 3.241)	0.2778
HYPERKALAEMIA	300	12 (4.0)	288 (96.0)	N.A. (N.A., N.A.)	284	7 (2.5)	277 (97.5)	N.A. (N.A., N.A.)	1.406 (0.536, 3.688)	0.4863
HYPERGLYCAEMIA	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	12 (4.2)	272 (95.8)	N.A. (N.A., N.A.)	0.795 (0.343, 1.841)	0.5922

April 2020 DBL.
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MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
HYPOKALAEMIA	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	1.369 (0.435, 4.307)	0.5892
HYPOMAGNESAEMIA	300	4 (1.3)	296 (98.7)	N.A. (N.A., N.A.)	284	12 (4.2)	272 (95.8)	N.A. (N.A., N.A.)	0.324 (0.105, 1.006)	0.0399
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	300	118 (39.3)	182 (60.7)	13.34 (9.63, N.A.)	284	47 (16.5)	237 (83.5)	N.A. (N.A., N.A.)	2.366 (1.673, 3.346)	<0.0001
ARTHRALGIA	300	41 (13.7)	259 (86.3)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	6.015 (2.333, 15.509)	<0.0001
MYALGIA	300	24 (8.0)	276 (92.0)	N.A. (N.A., N.A.)	284	7 (2.5)	277 (97.5)	N.A. (N.A., N.A.)	2.539 (1.062, 6.067)	0.0300
BACK PAIN	300	21 (7.0)	279 (93.0)	N.A. (N.A., N.A.)	284	14 (4.9)	270 (95.1)	N.A. (N.A., N.A.)	1.367 (0.685, 2.728)	0.3754
PAIN IN EXTREMITY	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	9 (3.2)	275 (96.8)	N.A. (N.A., N.A.)	1.245 (0.523, 2.963)	0.6192

April 2020 DBL.
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If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
MUSCULOSKELETAL PAIN	300	16 (5.3)	284 (94.7)	N.A. (N.A., N.A.)	284	6 (2.1)	278 (97.9)	N.A. (N.A., N.A.)	1.553 (0.562, 4.294)	0.3923
MUSCULOSKELETAL CHEST PAIN	300	14 (4.7)	286 (95.3)	N.A. (N.A., N.A.)	284	6 (2.1)	278 (97.9)	N.A. (N.A., N.A.)	1.942 (0.729, 5.175)	0.1764
INVESTIGATIONS	300	107 (35.7)	193 (64.3)	19.98 (14.78, N.A.)	284	71 (25.0)	213 (75.0)	N.A. (N.A., N.A.)	1.302 (0.955, 1.776)	0.0942
BLOOD CREATININE INCREASED	300	27 (9.0)	273 (91.0)	N.A. (N.A., N.A.)	284	18 (6.3)	266 (93.7)	N.A. (N.A., N.A.)	1.091 (0.577, 2.062)	0.7879
LIPASE INCREASED	300	27 (9.0)	273 (91.0)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	5.087 (1.740, 14.877)	0.0009
AMYLASE INCREASED	300	24 (8.0)	276 (92.0)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	4.255 (1.433, 12.633)	0.0045
ALANINE AMINOTRANSFERASE INCREASED	300	22 (7.3)	278 (92.7)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	4.694 (1.596, 13.806)	0.0020

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If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
BLOOD ALKALINE PHOSPHATASE INCREASED	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	4.535 (1.303, 15.781)	0.0091
WEIGHT DECREASED	300	17 (5.7)	283 (94.3)	N.A. (N.A., N.A.)	284	23 (8.1)	261 (91.9)	N.A. (N.A., N.A.)	0.538 (0.274, 1.055)	0.0671
ASPARTATE AMINOTRANSFERASE INCREASED	300	16 (5.3)	284 (94.7)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	13.151 (1.719, 100.591)	0.0013
NERVOUS SYSTEM DISORDERS	300	92 (30.7)	208 (69.3)	N.A. (16.99, N.A.)	284	70 (24.6)	214 (75.4)	N.A. (N.A., N.A.)	1.009 (0.727, 1.399)	0.9622
HEADACHE	300	24 (8.0)	276 (92.0)	N.A. (N.A., N.A.)	284	12 (4.2)	272 (95.8)	N.A. (N.A., N.A.)	1.670 (0.819, 3.404)	0.1540
DIZZINESS	300	16 (5.3)	284 (94.7)	N.A. (N.A., N.A.)	284	10 (3.5)	274 (96.5)	N.A. (N.A., N.A.)	1.168 (0.506, 2.698)	0.7157
DYSGEUSIA	300	15 (5.0)	285 (95.0)	N.A. (N.A., N.A.)	284	22 (7.7)	262 (92.3)	N.A. (N.A., N.A.)	0.387 (0.179, 0.835)	0.0120

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If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
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Time-Adjusted Analyses of Adverse Events for
Adverse Events
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All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
NEUROPATHY PERIPHERAL	300	3 (1.0)	297 (99.0)	N.A. (N.A., N.A.)	284	15 (5.3)	269 (94.7)	N.A. (N.A., N.A.)	0.128 (0.029, 0.559)	0.0012
BLOOD AND LYMPHATIC SYSTEM DISORDERS	300	66 (22.0)	234 (78.0)	N.A. (N.A., N.A.)	284	170 (59.9)	114 (40.1)	2.63 (2.07, 3.38)	0.222 (0.163, 0.303)	<0.0001
ANAEMIA	300	44 (14.7)	256 (85.3)	N.A. (N.A., N.A.)	284	120 (42.3)	164 (57.7)	N.A. (6.77, N.A.)	0.262 (0.182, 0.378)	<0.0001
NEUTROPENIA	300	6 (2.0)	294 (98.0)	N.A. (N.A., N.A.)	284	79 (27.8)	205 (72.2)	N.A. (N.A., N.A.)	0.041 (0.015, 0.111)	<0.0001
THROMBOCYTOPENIA	300	5 (1.7)	295 (98.3)	N.A. (N.A., N.A.)	284	32 (11.3)	252 (88.7)	N.A. (N.A., N.A.)	0.112 (0.040, 0.318)	<0.0001
LEUKOPENIA	300	0	300 (100.0)	N.A. (N.A., N.A.)	284	25 (8.8)	259 (91.2)	N.A. (N.A., N.A.)	N.M.E.	<0.0001
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	300	62 (20.7)	238 (79.3)	N.A. (N.A., N.A.)	284	48 (16.9)	236 (83.1)	N.A. (N.A., N.A.)	0.826 (0.544, 1.253)	0.3665

April 2020 DBL.
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If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
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by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
MALIGNANT NEOPLASM PROGRESSION	300	52 (17.3)	248 (82.7)	N.A. (N.A., N.A.)	284	41 (14.4)	243 (85.6)	N.A. (N.A., N.A.)	0.831 (0.529, 1.305)	0.4195
ENDOCRINE DISORDERS	300	58 (19.3)	242 (80.7)	N.A. (N.A., N.A.)	284	7 (2.5)	277 (97.5)	N.A. (N.A., N.A.)	7.608 (3.452, 16.767)	<0.0001
HYPOTHYROIDISM	300	38 (12.7)	262 (87.3)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	11.629 (3.572, 37.862)	<0.0001
HYPERTHYROIDISM	300	12 (4.0)	288 (96.0)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	5.805 (1.299, 25.933)	0.0090
PSYCHIATRIC DISORDERS	300	55 (18.3)	245 (81.7)	N.A. (N.A., N.A.)	284	42 (14.8)	242 (85.2)	N.A. (N.A., N.A.)	1.142 (0.756, 1.725)	0.5248
INSOMNIA	300	28 (9.3)	272 (90.7)	N.A. (N.A., N.A.)	284	16 (5.6)	268 (94.4)	N.A. (N.A., N.A.)	1.710 (0.925, 3.161)	0.0834
ANXIETY	300	15 (5.0)	285 (95.0)	N.A. (N.A., N.A.)	284	9 (3.2)	275 (96.8)	N.A. (N.A., N.A.)	1.284 (0.541, 3.048)	0.5696

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
DEPRESSION	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	1.770 (0.595, 5.265)	0.2983
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	300	51 (17.0)	249 (83.0)	N.A. (N.A., N.A.)	284	13 (4.6)	271 (95.4)	N.A. (N.A., N.A.)	2.898 (1.542, 5.444)	0.0005
INFUSION RELATED REACTION	300	25 (8.3)	275 (91.7)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	11.205 (2.642, 47.528)	<0.0001
CARDIAC DISORDERS	300	42 (14.0)	258 (86.0)	N.A. (N.A., N.A.)	284	16 (5.6)	268 (94.4)	N.A. (N.A., N.A.)	1.958 (1.075, 3.566)	0.0252
ATRIAL FIBRILLATION	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	1.967 (0.592, 6.534)	0.2604
VASCULAR DISORDERS	300	40 (13.3)	260 (86.7)	N.A. (N.A., N.A.)	284	23 (8.1)	261 (91.9)	N.A. (N.A., N.A.)	1.423 (0.835, 2.424)	0.1945
HYPERTENSION	300	15 (5.0)	285 (95.0)	N.A. (N.A., N.A.)	284	8 (2.8)	276 (97.2)	N.A. (N.A., N.A.)	1.212 (0.479, 3.065)	0.6848

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
HEPATOBILIARY DISORDERS	300	39 (13.0)	261 (87.0)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	5.365 (2.067, 13.924)	0.0001
HEPATIC FUNCTION ABNORMAL	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	3.868 (0.821, 18.221)	0.0652
RENAL AND URINARY DISORDERS	300	35 (11.7)	265 (88.3)	N.A. (N.A., N.A.)	284	22 (7.7)	262 (92.3)	N.A. (N.A., N.A.)	1.047 (0.588, 1.865)	0.8764
ACUTE KIDNEY INJURY	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	1.389 (0.442, 4.369)	0.5721
EYE DISORDERS	300	32 (10.7)	268 (89.3)	N.A. (N.A., N.A.)	284	45 (15.8)	239 (84.2)	N.A. (N.A., N.A.)	0.418 (0.250, 0.698)	0.0006
LACRIMATION INCREASED	300	1 (0.3)	299 (99.7)	N.A. (N.A., N.A.)	284	19 (6.7)	265 (93.3)	N.A. (N.A., N.A.)	0.026 (0.003, 0.246)	<0.0001
IMMUNE SYSTEM DISORDERS	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	9 (3.2)	275 (96.8)	N.A. (N.A., N.A.)	1.657 (0.731, 3.758)	0.2239

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

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Time-Adjusted Analyses of Adverse Events for
Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
HYPERSENSITIVITY	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	2.093 (0.726, 6.039)	0.1648
EAR AND LABYRINTH DISORDERS	300	17 (5.7)	283 (94.3)	N.A. (N.A., N.A.)	284	17 (6.0)	267 (94.0)	N.A. (N.A., N.A.)	0.679 (0.326, 1.415)	0.2987

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:00

Anhang 4-G 3.2.2: Ergebnisse für Endpunkte UE Grad ≥ 3 auf SOC/PT-Ebene aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
TOTAL SUBJECTS WITH AN EVENT	300	200 (66.7)	100 (33.3)	6.11 (4.21, 8.11)	284	158 (55.6)	126 (44.4)	4.99 (3.06, 6.54)	0.878 (0.704, 1.095)	0.2498
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	300	52 (17.3)	248 (82.7)	N.A. (N.A., N.A.)	284	42 (14.8)	242 (85.2)	N.A. (N.A., N.A.)	0.827 (0.529, 1.292)	0.4024
MALIGNANT NEOPLASM PROGRESSION	300	48 (16.0)	252 (84.0)	N.A. (N.A., N.A.)	284	40 (14.1)	244 (85.9)	N.A. (N.A., N.A.)	0.795 (0.501, 1.261)	0.3285
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	300	35 (11.7)	265 (88.3)	N.A. (N.A., N.A.)	284	24 (8.5)	260 (91.5)	N.A. (N.A., N.A.)	1.191 (0.693, 2.046)	0.5265
DYSPNOEA	300	9 (3.0)	291 (97.0)	N.A. (N.A., N.A.)	284	13 (4.6)	271 (95.4)	N.A. (N.A., N.A.)	0.528 (0.211, 1.325)	0.1664
INVESTIGATIONS	300	34 (11.3)	266 (88.7)	N.A. (N.A., N.A.)	284	10 (3.5)	274 (96.5)	N.A. (N.A., N.A.)	2.148 (1.017, 4.538)	0.0400

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:26

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Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
LIPASE INCREASED	300	17 (5.7)	283 (94.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	11.718 (1.523, 90.150)	0.0026
GASTROINTESTINAL DISORDERS	300	32 (10.7)	268 (89.3)	N.A. (N.A., N.A.)	284	24 (8.5)	260 (91.5)	N.A. (N.A., N.A.)	0.688 (0.372, 1.272)	0.2306
DIARRHOEA	300	12 (4.0)	288 (96.0)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	3.828 (0.812, 18.040)	0.0683
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	300	32 (10.7)	268 (89.3)	N.A. (N.A., N.A.)	284	35 (12.3)	249 (87.7)	N.A. (N.A., N.A.)	0.662 (0.394, 1.112)	0.1163
ASTHENIA	300	4 (1.3)	296 (98.7)	N.A. (N.A., N.A.)	284	13 (4.6)	271 (95.4)	N.A. (N.A., N.A.)	0.226 (0.066, 0.769)	0.0095
INFECTIONS AND INFESTATIONS	300	29 (9.7)	271 (90.3)	N.A. (N.A., N.A.)	284	14 (4.9)	270 (95.1)	N.A. (N.A., N.A.)	1.327 (0.665, 2.645)	0.4205
PNEUMONIA	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	6 (2.1)	278 (97.9)	N.A. (N.A., N.A.)	1.144 (0.384, 3.404)	0.8090

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:26

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Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
METABOLISM AND NUTRITION DISORDERS	300	27 (9.0)	273 (91.0)	N.A. (N.A., N.A.)	284	24 (8.5)	260 (91.5)	N.A. (N.A., N.A.)	0.669 (0.359, 1.247)	0.2028
BLOOD AND LYMPHATIC SYSTEM DISORDERS	300	21 (7.0)	279 (93.0)	N.A. (N.A., N.A.)	284	86 (30.3)	198 (69.7)	N.A. (N.A., N.A.)	0.137 (0.078, 0.239)	<0.0001
ANAEMIA	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	39 (13.7)	245 (86.3)	N.A. (N.A., N.A.)	0.170 (0.078, 0.369)	<0.0001
NEUTROPENIA	300	4 (1.3)	296 (98.7)	N.A. (N.A., N.A.)	284	45 (15.8)	239 (84.2)	N.A. (N.A., N.A.)	0.039 (0.009, 0.159)	<0.0001
THROMBOCYTOPENIA	300	4 (1.3)	296 (98.7)	N.A. (N.A., N.A.)	284	11 (3.9)	273 (96.1)	N.A. (N.A., N.A.)	0.173 (0.038, 0.782)	0.0098
HEPATOBILIARY DISORDERS	300	20 (6.7)	280 (93.3)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0003
CARDIAC DISORDERS	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	6 (2.1)	278 (97.9)	N.A. (N.A., N.A.)	1.763 (0.652, 4.769)	0.2574

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:26

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Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
NERVOUS SYSTEM DISORDERS	300	15 (5.0)	285 (95.0)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	3.565 (0.994, 12.785)	0.0370
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	300	14 (4.7)	286 (95.3)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	8.669 (1.098, 68.438)	0.0135
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	4.424 (0.957, 20.447)	0.0373
VASCULAR DISORDERS	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	2 (0.7)	282 (99.3)	N.A. (N.A., N.A.)	3.243 (0.670, 15.701)	0.1221
RENAL AND URINARY DISORDERS	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	1.653 (0.396, 6.897)	0.4858

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:26

Anhang 4-G 3.2.3: Ergebnisse für Endpunkte SUE auf SOC/PT-Ebene aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
TOTAL SUBJECTS WITH AN EVENT	300	187 (62.3)	113 (37.7)	7.89 (5.26, 9.66)	284	105 (37.0)	179 (63.0)	N.A. (N.A., N.A.)	1.446 (1.122, 1.862)	0.0042
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	300	56 (18.7)	244 (81.3)	N.A. (N.A., N.A.)	284	44 (15.5)	240 (84.5)	N.A. (N.A., N.A.)	0.796 (0.513, 1.236)	0.3087
MALIGNANT NEOPLASM PROGRESSION	300	51 (17.0)	249 (83.0)	N.A. (N.A., N.A.)	284	41 (14.4)	243 (85.6)	N.A. (N.A., N.A.)	0.808 (0.513, 1.273)	0.3559
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	300	43 (14.3)	257 (85.7)	N.A. (N.A., N.A.)	284	20 (7.0)	264 (93.0)	N.A. (N.A., N.A.)	1.731 (0.999, 3.000)	0.0476
INFECTIONS AND INFESTATIONS	300	36 (12.0)	264 (88.0)	N.A. (N.A., N.A.)	284	14 (4.9)	270 (95.1)	N.A. (N.A., N.A.)	1.598 (0.822, 3.107)	0.1629
PNEUMONIA	300	14 (4.7)	286 (95.3)	N.A. (N.A., N.A.)	284	6 (2.1)	278 (97.9)	N.A. (N.A., N.A.)	1.476 (0.525, 4.148)	0.4575

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:33

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Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
GASTROINTESTINAL DISORDERS	300	32 (10.7)	268 (89.3)	N.A. (N.A., N.A.)	284	12 (4.2)	272 (95.8)	N.A. (N.A., N.A.)	1.350 (0.641, 2.842)	0.4283
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	300	31 (10.3)	269 (89.7)	N.A. (N.A., N.A.)	284	19 (6.7)	265 (93.3)	N.A. (N.A., N.A.)	1.085 (0.584, 2.016)	0.7989
PYREXIA	300	16 (5.3)	284 (94.7)	N.A. (N.A., N.A.)	284	4 (1.4)	280 (98.6)	N.A. (N.A., N.A.)	2.445 (0.768, 7.783)	0.1182
CARDIAC DISORDERS	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	5 (1.8)	279 (98.2)	N.A. (N.A., N.A.)	2.500 (0.891, 7.014)	0.0714
HEPATOBILIARY DISORDERS	300	19 (6.3)	281 (93.7)	N.A. (N.A., N.A.)	284	0	284 (100.0)	N.A. (N.A., N.A.)	N.M.E.	0.0003
NERVOUS SYSTEM DISORDERS	300	18 (6.0)	282 (94.0)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	12.830 (1.678, 98.101)	0.0015
RENAL AND URINARY DISORDERS	300	13 (4.3)	287 (95.7)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	3.680 (1.027, 13.189)	0.0320

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:33

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Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
by SOC/PT on Hazard Ratio
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi Censored Patients n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo Censored Patients n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] (2)	Nivo + Ipi vs. Chemo P-value (3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	300	12 (4.0)	288 (96.0)	N.A. (N.A., N.A.)	284	3 (1.1)	281 (98.9)	N.A. (N.A., N.A.)	2.863 (0.775, 10.580)	0.0988
METABOLISM AND NUTRITION DISORDERS	300	11 (3.7)	289 (96.3)	N.A. (N.A., N.A.)	284	8 (2.8)	276 (97.2)	N.A. (N.A., N.A.)	0.608 (0.199, 1.859)	0.3780
ENDOCRINE DISORDERS	300	10 (3.3)	290 (96.7)	N.A. (N.A., N.A.)	284	1 (0.4)	283 (99.6)	N.A. (N.A., N.A.)	7.757 (0.970, 62.026)	0.0222
BLOOD AND LYMPHATIC SYSTEM DISORDERS	300	7 (2.3)	293 (97.7)	N.A. (N.A., N.A.)	284	16 (5.6)	268 (94.4)	N.A. (N.A., N.A.)	0.298 (0.109, 0.813)	0.0120

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
If there are no patients with events in Nivo + Ipi or Chemotherapy, presentation of HR as n.m.e.
(1) KME of median time to first AE
(2) Stratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemotherapy.
(3) Log-rank Test stratefied by histolgoy per IRT and sex.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-teasocpthru-ebr2252.sas 02DEC2020:21:41:33

Anhang 4-G 3.2.4: Ergebnisse für Endpunkte Therapieabbruch wegen UE auf SOC/PT-Ebene aus CA209-743 – Inzidenzen

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AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N = 300 Any Grade	Nivo + Ipi N = 300 Grade 3-4	Nivo + Ipi N = 300 Grade 5	Chemo N = 284 Any Grade	Chemo N = 284 Grade 3-4	Chemo N = 284 Grade 5
TOTAL SUBJECTS WITH AN EVENT	98 (32.7)	64 (21.3)	3 (1.0)	61 (21.5)	29 (10.2)	2 (0.7)
Gastrointestinal disorders	18 (6.0)	14 (4.7)	0	10 (3.5)	5 (1.8)	0
Colitis	7 (2.3)	7 (2.3)	0	1 (0.4)	1 (0.4)	0
Diarrhoea	7 (2.3)	4 (1.3)	0	0	0	0
Pancreatitis	2 (0.7)	0	0	0	0	0
Abdominal pain	1 (0.3)	0	0	1 (0.4)	0	0
Enterocolitis	1 (0.3)	1 (0.3)	0	0	0	0
Gastritis erosive	1 (0.3)	1 (0.3)	0	0	0	0
Intestinal obstruction	1 (0.3)	1 (0.3)	0	0	0	0
Colitis ulcerative	0	0	0	1 (0.4)	1 (0.4)	0
Constipation	0	0	0	1 (0.4)	0	0
Nausea	0	0	0	5 (1.8)	0	0
Subileus	0	0	0	1 (0.4)	1 (0.4)	0
Vomiting	0	0	0	3 (1.1)	2 (0.7)	0
Hepatobiliary disorders	16 (5.3)	12 (4.0)	0	0	0	0
Hepatic function abnormal	4 (1.3)	4 (1.3)	0	0	0	0
Hepatitis	3 (1.0)	2 (0.7)	0	0	0	0
Immune-mediated hepatitis	3 (1.0)	2 (0.7)	0	0	0	0
Drug-induced liver injury	2 (0.7)	2 (0.7)	0	0	0	0
Autoimmune hepatitis	1 (0.3)	0	0	0	0	0
Cholecystitis	1 (0.3)	1 (0.3)	0	0	0	0
Hepatocellular injury	1 (0.3)	1 (0.3)	0	0	0	0
Hepatotoxicity	1 (0.3)	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	12 (4.0)	5 (1.7)	0	1 (0.4)	1 (0.4)	0
Pneumonitis	7 (2.3)	3 (1.0)	0	0	0	0
Dyspnoea	2 (0.7)	0	0	0	0	0

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0
Includes events reported between first dose and 100 days after last dose of study therapy.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltde-ebr2252.sas 20NOV2020:11:15:27

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AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N = 300 Any Grade	Nivo + Ipi N = 300 Grade 3-4	Nivo + Ipi N = 300 Grade 5	Chemo N = 284 Any Grade	Chemo N = 284 Grade 3-4	Chemo N = 284 Grade 5
Immune-mediated pneumonitis	1 (0.3)	0	0	0	0	0
Interstitial lung disease	1 (0.3)	1 (0.3)	0	0	0	0
Respiratory failure	1 (0.3)	1 (0.3)	0	0	0	0
Acute respiratory failure	0	0	0	1 (0.4)	1 (0.4)	0
Renal and urinary disorders	7 (2.3)	4 (1.3)	0	2 (0.7)	0	0
Acute kidney injury	3 (1.0)	1 (0.3)	0	1 (0.4)	0	0
Chronic kidney disease	1 (0.3)	1 (0.3)	0	1 (0.4)	0	0
Nephrotic syndrome	1 (0.3)	1 (0.3)	0	0	0	0
Renal failure	1 (0.3)	0	0	0	0	0
Renal impairment	1 (0.3)	1 (0.3)	0	0	0	0
Investigations	6 (2.0)	2 (0.7)	0	3 (1.1)	0	0
Alanine aminotransferase increased	3 (1.0)	2 (0.7)	0	0	0	0
Aspartate aminotransferase increased	2 (0.7)	1 (0.3)	0	0	0	0
Blood creatinine increased	2 (0.7)	0	0	2 (0.7)	0	0
Amylase increased	1 (0.3)	0	0	0	0	0
Weight decreased	0	0	0	1 (0.4)	0	0
Musculoskeletal and connective tissue disorders	6 (2.0)	1 (0.3)	0	1 (0.4)	0	0
Arthralgia	2 (0.7)	0	0	0	0	0
Myositis	2 (0.7)	1 (0.3)	0	0	0	0
Myopathy	1 (0.3)	0	0	0	0	0
Polymyalgia rheumatica	1 (0.3)	0	0	0	0	0
Bone pain	0	0	0	1 (0.4)	0	0
Cardiac disorders	5 (1.7)	4 (1.3)	1 (0.3)	2 (0.7)	2 (0.7)	0
Cardiac failure	1 (0.3)	1 (0.3)	0	0	0	0
Cardiomyopathy	1 (0.3)	1 (0.3)	0	0	0	0

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0
Includes events reported between first dose and 100 days after last dose of study therapy.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltde-ebr2252.sas 20NOV2020:11:15:27

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AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N = 300 Any Grade	Nivo + Ipi N = 300 Grade 3-4	Nivo + Ipi N = 300 Grade 5	Chemo N = 284 Any Grade	Chemo N = 284 Grade 3-4	Chemo N = 284 Grade 5
Myocardial infarction	1 (0.3)	0	1 (0.3)	1 (0.4)	1 (0.4)	0
Myocarditis	1 (0.3)	1 (0.3)	0	0	0	0
Pleuropericarditis	1 (0.3)	1 (0.3)	0	0	0	0
Cardiac arrest	0	0	0	1 (0.4)	1 (0.4)	0
General disorders and administration site conditions	5 (1.7)	3 (1.0)	0	13 (4.6)	7 (2.5)	0
Fatigue	2 (0.7)	1 (0.3)	0	5 (1.8)	1 (0.4)	0
Chest pain	1 (0.3)	1 (0.3)	0	0	0	0
Malaise	1 (0.3)	0	0	1 (0.4)	0	0
Performance status decreased	1 (0.3)	1 (0.3)	0	0	0	0
Asthenia	0	0	0	6 (2.1)	5 (1.8)	0
General physical health deterioration	0	0	0	1 (0.4)	1 (0.4)	0
Infections and infestations	5 (1.7)	2 (0.7)	2 (0.7)	3 (1.1)	2 (0.7)	0
Bronchitis	1 (0.3)	1 (0.3)	0	0	0	0
Clostridium difficile colitis	1 (0.3)	0	0	0	0	0
Encephalitis	1 (0.3)	0	1 (0.3)	0	0	0
Pneumonia	1 (0.3)	1 (0.3)	0	1 (0.4)	0	0
Sepsis	1 (0.3)	0	1 (0.3)	2 (0.7)	2 (0.7)	0
Injury, poisoning and procedural complications	5 (1.7)	3 (1.0)	0	0	0	0
Infusion related reaction	5 (1.7)	3 (1.0)	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (1.7)	5 (1.7)	0	3 (1.1)	2 (0.7)	1 (0.4)
Malignant neoplasm progression	4 (1.3)	4 (1.3)	0	3 (1.1)	2 (0.7)	1 (0.4)
Mesothelioma malignant	1 (0.3)	1 (0.3)	0	0	0	0

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0
Includes events reported between first dose and 100 days after last dose of study therapy.
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AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N = 300 Any Grade	Nivo + Ipi N = 300 Grade 3-4	Nivo + Ipi N = 300 Grade 5	Chemo N = 284 Any Grade	Chemo N = 284 Grade 3-4	Chemo N = 284 Grade 5
Nervous system disorders	5 (1.7)	3 (1.0)	0	1 (0.4)	0	0
Limbic encephalitis	1 (0.3)	0	0	0	0	0
Myasthenic syndrome	1 (0.3)	1 (0.3)	0	0	0	0
Myelitis transverse	1 (0.3)	1 (0.3)	0	0	0	0
Neuropathy peripheral	1 (0.3)	0	0	1 (0.4)	0	0
Polyneuropathy	1 (0.3)	1 (0.3)	0	0	0	0
Blood and lymphatic system disorders	4 (1.3)	2 (0.7)	0	24 (8.5)	13 (4.6)	1 (0.4)
Anaemia	1 (0.3)	0	0	13 (4.6)	5 (1.8)	0
Neutropenia	1 (0.3)	1 (0.3)	0	5 (1.8)	3 (1.1)	0
Thrombocytopenia	1 (0.3)	0	0	5 (1.8)	5 (1.8)	0
Thrombocytopenic purpura	1 (0.3)	1 (0.3)	0	0	0	0
Bone marrow failure	0	0	0	1 (0.4)	0	1 (0.4)
Pancytopenia	0	0	0	1 (0.4)	1 (0.4)	0
Endocrine disorders	3 (1.0)	1 (0.3)	0	0	0	0
Adrenal insufficiency	2 (0.7)	1 (0.3)	0	0	0	0
Hypothalamo-pituitary disorder	1 (0.3)	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (0.7)	1 (0.3)	0	0	0	0
Pruritus	1 (0.3)	1 (0.3)	0	0	0	0
Psoriasis	1 (0.3)	0	0	0	0	0
Vascular disorders	2 (0.7)	1 (0.3)	0	1 (0.4)	0	0
Superior vena cava syndrome	1 (0.3)	0	0	0	0	0
Temporal arteritis	1 (0.3)	1 (0.3)	0	0	0	0
Hypotension	0	0	0	1 (0.4)	0	0
Eye disorders	1 (0.3)	1 (0.3)	0	0	0	0
Cataract	1 (0.3)	0	0	0	0	0

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0
Includes events reported between first dose and 100 days after last dose of study therapy.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltde-ebr2252.sas 20NOV2020:11:15:27

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AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) / Preferred Term (%)	Nivo + Ipi N = 300 Any Grade	Nivo + Ipi N = 300 Grade 3-4	Nivo + Ipi N = 300 Grade 5	Chemo N = 284 Any Grade	Chemo N = 284 Grade 3-4	Chemo N = 284 Grade 5
Iritis	1 (0.3)	1 (0.3)	0	0	0	0
Metabolism and nutrition disorders	1 (0.3)	1 (0.3)	0	1 (0.4)	0	0
Diabetes mellitus	1 (0.3)	1 (0.3)	0	0	0	0
Decreased appetite	0	0	0	1 (0.4)	0	0
Ear and labyrinth disorders	0	0	0	4 (1.4)	0	0
Hypoacusis	0	0	0	3 (1.1)	0	0
Ototoxicity	0	0	0	1 (0.4)	0	0
Tinnitus	0	0	0	1 (0.4)	0	0
Immune system disorders	0	0	0	1 (0.4)	0	0
Hypersensitivity	0	0	0	1 (0.4)	0	0

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0
Includes events reported between first dose and 100 days after last dose of study therapy.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-aeltde-ebr2252.sas 20NOV2020:11:15:27

Anhang 4-G 4: Subgruppenanalysen

Anhang 4-G 4.1: Subgruppenanalysen zu Endpunkten des Hauptteils aus CA209-743

Anhang 4-G 4.1.1: Subgruppenanalysen für Endpunkte Mortalität – Gesamtüberleben (OS) aus CA209-743

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Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall survival	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
OVERALL	303	200 (66.0)	18.07 (16.82, 21.45)	302	219 (72.5)	14.09 (12.45, 16.23)	0.75 (0.62, 0.91) 0.0030	
AGE CATEGORIZATION								0.1516
< 65	71	45 (63.4)	17.18 (13.11, 29.24)	96	66 (68.8)	13.27 (10.61, 18.30)	0.76 (0.52, 1.11) 0.1604	
>= 65 AND < 75	154	99 (64.3)	20.27 (17.28, 24.64)	127	98 (77.2)	14.88 (11.63, 17.91)	0.63 (0.48, 0.83) 0.0012	
>= 75	78	56 (71.8)	16.92 (11.04, 20.83)	79	55 (69.6)	15.38 (11.73, 18.43)	1.02 (0.70, 1.48) 0.9272	
SEX								0.8753
MALE	234	157 (67.1)	17.51 (16.23, 20.67)	233	173 (74.2)	13.73 (11.73, 15.54)	0.74 (0.60, 0.92) 0.0064	
FEMALE	69	43 (62.3)	21.45 (15.70, 25.92)	69	46 (66.7)	18.04 (12.65, 23.79)	0.76 (0.50, 1.16) 0.1991	

April 2020 DBL.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub01-ebr2252.sas 04FEB2021:14:04:34

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Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall survival	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
RACE								0.5912
WHITE	266	173 (65.0)	18.83 (17.08, 21.91)	250	178 (71.2)	14.98 (12.45, 16.69)	0.74 (0.60, 0.91) 0.0046	
ASIAN	26	21 (80.8)	12.19 (9.79, 17.94)	39	31 (79.5)	12.67 (8.87, 17.18)	0.97 (0.56, 1.69) 0.9230	
OTHER	11	6 (54.5)	20.83 (3.65, N.A.)	13	10 (76.9)	13.04 (7.26, 21.72)	0.58 (0.21, 1.60) 0.2840	
REGION								0.5839
NORTH AMERICA	32	18 (56.3)	20.96 (16.16, 28.19)	27	21 (77.8)	12.65 (7.13, 17.58)	0.54 (0.28, 1.03) 0.0557	
EUROPE	177	116 (65.5)	19.12 (17.05, 24.34)	175	120 (68.6)	15.15 (12.45, 19.09)	0.77 (0.60, 0.99) 0.0443	
ASIA	26	21 (80.8)	12.19 (9.79, 17.94)	39	31 (79.5)	12.67 (8.87, 17.18)	0.97 (0.56, 1.69) 0.9230	
REST OF WORLD	68	45 (66.2)	17.51 (11.79, 25.43)	61	47 (77.0)	13.57 (9.30, 18.07)	0.74 (0.49, 1.11) 0.1487	

April 2020 DBL.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub01-ebr2252.sas 04FEB2021:14:04:34

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Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall survival	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 PERFORMANCE STATUS								0.1163
0	114	76 (66.7)	20.67 (17.48, 24.90)	128	81 (63.3)	19.52 (15.21, 22.77)	0.87 (0.64, 1.19) 0.3807	
>= 1	189	124 (65.6)	17.05 (14.09, 20.83)	174	138 (79.3)	11.63 (8.97, 13.90)	0.66 (0.52, 0.85) 0.0009	
IVRS HISTOLOGY								0.0029**
EPITHELIOID	236	157 (66.5)	18.73 (17.05, 21.72)	235	164 (69.8)	16.23 (14.09, 19.15)	0.85 (0.68, 1.06) 0.1506	
NON-EPITHELIOID	67	43 (64.2)	16.89 (11.83, 25.20)	67	55 (82.1)	8.80 (7.62, 11.76)	0.46 (0.31, 0.70) 0.0002	

April 2020 DBL.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub01-ebr2252.sas 04FEB2021:14:04:34

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Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall survival	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 STUDY ENTRY								0.0258**
STAGE I	12	10 (83.3)	16.77 (2.46, 24.34)	20	12 (60.0)	20.53 (9.30, 31.41)	1.43 (0.62, 3.32) 0.4027	
STAGE II	23	16 (69.6)	24.77 (15.70, 28.55)	22	8 (36.4)	N.A. (16.46, N.A.)	2.00 (0.86, 4.69) 0.1018	
STAGE III	103	60 (58.3)	23.92 (18.04, 27.30)	106	81 (76.4)	16.33 (12.68, 20.30)	0.61 (0.44, 0.86) 0.0040	
STAGE IV	160	110 (68.8)	16.69 (13.34, 18.56)	149	115 (77.2)	10.81 (9.13, 13.67)	0.67 (0.52, 0.87) 0.0028	
NOT REPORTED	5	4 (80.0)	16.30 (6.21, N.A.)	5	3 (60.0)	16.03 (9.03, N.A.)	N.M.E.	

April 2020 DBL.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ef-ossub01-ebr2252.sas 04FEB2021:14:04:34

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Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall survival	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
TOBACCO USE								0.6393
NEVER	127	80 (63.0)	17.91 (14.06, 25.20)	122	91 (74.6)	14.13 (11.76, 17.58)	0.71 (0.53, 0.96) 0.0278	
FORMER	155	111 (71.6)	17.51 (15.47, 20.34)	163	119 (73.0)	13.67 (10.81, 17.91)	0.84 (0.65, 1.09) 0.1871	
CURRENT	18	8 (44.4)	N.A. (18.07, N.A.)	8	5 (62.5)	21.29 (8.84, N.A.)	0.47 (0.15, 1.45) 0.1802	
UNKNOWN	3	1 (33.3)	N.A. (16.16, N.A.)	9	4 (44.4)	12.83 (3.71, N.A.)	0.39 (0.04, 3.52) 0.3837	
PRIOR RADIOTHERAPY								0.3184
YES	29	20 (69.0)	17.05 (7.95, 24.90)	28	18 (64.3)	19.55 (8.80, 27.43)	1.00 (0.53, 1.90) 0.9885	
NO	274	180 (65.7)	18.73 (16.89, 21.55)	274	201 (73.4)	14.09 (12.45, 15.57)	0.72 (0.59, 0.88) 0.0015	

April 2020 DBL.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Analyses of Overall Survival
All Randomized Subjects

Overall survival	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	302	200 (66.2)	N.M.E.	302	219 (72.5)	N.M.E.	N.M.E.	
PD-L1								0.1950
POSITIVE	232	150 (64.7)	18.04 (16.76, 21.45)	219	157 (71.7)	13.27 (11.56, 15.38)	0.69 (0.55, 0.87) 0.0014	
NEGATIVE	57	40 (70.2)	17.28 (10.09, 24.34)	78	58 (74.4)	16.49 (13.37, 20.53)	0.94 (0.62, 1.40) 0.7431	
NOT REPORTED	14	10 (71.4)	24.05 (5.32, 27.30)	5	4 (80.0)	17.91 (3.32, N.A.)	N.M.E.	

April 2020 DBL.
HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified Log-rank Test
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Anhang 4-G 4.1.2: Subgruppenanalysen für Endpunkte Morbidität und Lebensqualität aus CA209-743

Subgruppenanalysen für die Endpunkte Appetitlosigkeit, Fatigue, Husten, Dyspnoe, Schmerz, Symptombelastung, Aktivitätsbeeinträchtigung, allgemeine gesundheitsbezogene Lebensqualität, Index-Wert der krankheitsbedingten Symptome (MID 15 mm) und den Index-Wert der gesundheitsbezogenen Lebensqualität gemäß LCSS-Meso (MID 45 mm) sowie den Gesundheitszustand gemäß EQ-5D-VAS (MID 7 mm) – Zeit bis zur dauerhaften Verschlechterung

Anhang 4-G 4.1.2.1: Subgruppenanalysen für den Endpunkt Appetitlosigkeit gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.2: Subgroup Time to Definitive Deterioration LCSS: Anorexia (Appetite) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	70 (23.1%)	233 (76.9%)	27.76 (22.18, N.A.)	302	68 (22.5%)	234 (77.5%)	8.84 (7.89, N.A.)	0.565 (0.391, 0.817) 0.0024	
Age Category:										0.8102
< 65	71	14 (19.7%)	57 (80.3%)	N.A. (13.83, N.A.)	96	14 (14.6%)	82 (85.4%)	N.A. (7.69, N.A.)	0.820 (0.368, 1.828) 0.6276	
>= 65 and <75	154	36 (23.4%)	118 (76.6%)	25.82 (20.14, N.A.)	127	29 (22.8%)	98 (77.2%)	14.98 (7.72, N.A.)	0.539 (0.314, 0.926) 0.0253	
>= 75	78	20 (25.6%)	58 (74.4%)	27.76 (11.20, N.A.)	79	25 (31.6%)	54 (68.4%)	8.02 (7.43, 10.05)	0.558 (0.293, 1.060) 0.0749	
Gender:										0.7033
Male	234	50 (21.4%)	184 (78.6%)	27.76 (20.14, N.A.)	233	55 (23.6%)	178 (76.4%)	10.05 (8.02, N.A.)	0.561 (0.368, 0.853) 0.0069	
Female	69	20 (29.0%)	49 (71.0%)	24.18 (13.83, N.A.)	69	13 (18.8%)	56 (81.2%)	8.08 (7.72, 8.84)	0.614 (0.281, 1.340) 0.2203	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.2 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Anorexia (Appetite) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.9366
White	266	58 (21.8%)	208 (78.2%)	25.82 (22.18, N.A.)	250	51 (20.4%)	199 (79.6%)	8.84 (7.89, N.A.)	0.549 (0.363, 0.829) 0.0043	
Asian	26	10 (38.5%)	16 (61.5%)	20.14 (5.16, N.A.)	39	15 (38.5%)	24 (61.5%)	8.02 (5.91, N.A.)	0.686 (0.274, 1.717) 0.4209	
Other	11	2 (18.2%)	9 (81.8%)	N.A. (2.37, N.A.)	13	2 (15.4%)	11 (84.6%)	N.A. (7.69, N.A.)	1.243 (0.126, 12.260) 0.8522	
Region:										0.6528
North America	32	7 (21.9%)	25 (78.1%)	N.A. (5.52, N.A.)	27	7 (25.9%)	20 (74.1%)	5.32 (2.83, 7.89)	0.449 (0.145, 1.388) 0.1645	
EU	177	38 (21.5%)	139 (78.5%)	25.82 (22.18, N.A.)	175	37 (21.1%)	138 (78.9%)	8.84 (7.85, N.A.)	0.439 (0.264, 0.730) 0.0015	
Asia	26	10 (38.5%)	16 (61.5%)	20.14 (5.16, N.A.)	39	15 (38.5%)	24 (61.5%)	8.02 (5.91, N.A.)	0.686 (0.274, 1.717) 0.4209	
RoW	68	15 (22.1%)	53 (77.9%)	N.A. (16.36, N.A.)	61	9 (14.8%)	52 (85.2%)	N.A. (N.A., N.A.)	1.258 (0.540, 2.930) 0.5946	
ECOG Performance:										0.9754
0	114	20 (17.5%)	94 (82.5%)	N.A. (N.A., N.A.)	128	24 (18.8%)	104 (81.3%)	10.05 (8.84, N.A.)	0.470 (0.246, 0.898) 0.0223	
>= 1	189	50 (26.5%)	139 (73.5%)	24.18 (13.83, N.A.)	174	44 (25.3%)	130 (74.7%)	8.02 (7.59, 8.21)	0.598 (0.382, 0.936) 0.0244	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.2 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Anorexia (Appetite) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.1596*
Epithelioid	236	53 (22.5%)	183 (77.5%)	25.82 (22.18, N.A.)	235	48 (20.4%)	187 (79.6%)	14.98 (8.02, N.A.)	0.665 (0.434, 1.020) 0.0616	
Non-Epithelioid	67	17 (25.4%)	50 (74.6%)	27.76 (9.95, N.A.)	67	20 (29.9%)	47 (70.1%)	7.89 (4.63, 10.05)	0.368 (0.177, 0.767) 0.0076	
Disease Stage at Study Entry:										0.8943
Stage I	12	3 (25.0%)	9 (75.0%)	N.A. (1.38, N.A.)	20	7 (35.0%)	13 (65.0%)	8.08 (7.43, 14.98)	0.662 (0.168, 2.613) 0.5563	
Stage II	23	2 (8.7%)	21 (91.3%)	N.A. (12.25, N.A.)	22	3 (13.6%)	19 (86.4%)	N.A. (10.05, N.A.)	0.437 (0.065, 2.934) 0.3941	
Stage III	103	28 (27.2%)	75 (72.8%)	N.A. (16.33, N.A.)	106	22 (20.8%)	84 (79.2%)	8.84 (8.21, 8.84)	0.782 (0.419, 1.461) 0.4411	
Stage IV	160	36 (22.5%)	124 (77.5%)	25.82 (14.00, N.A.)	149	35 (23.5%)	114 (76.5%)	7.89 (7.52, N.A.)	0.483 (0.285, 0.818) 0.0068	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.2 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Anorexia (Appetite) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.6412
Never	127	30 (23.6%)	97 (76.4%)	24.18 (16.36, N.A.)	122	35 (28.7%)	87 (71.3%)	8.08 (7.72, 14.98)	0.519 (0.305, 0.884) 0.0159	
Former	155	34 (21.9%)	121 (78.1%)	25.82 (16.33, N.A.)	163	29 (17.8%)	134 (82.2%)	10.05 (7.85, N.A.)	0.683 (0.397, 1.176) 0.1689	
Current	18	6 (33.3%)	12 (66.7%)	27.76 (7.06, N.A.)	8	2 (25.0%)	6 (75.0%)	N.A. (1.41, N.A.)	0.402 (0.066, 2.459) 0.3242	
Prior Radiotherapy:										0.9458
Yes	29	4 (13.8%)	25 (86.2%)	27.76 (11.20, 27.76)	28	4 (14.3%)	24 (85.7%)	N.A. (7.39, N.A.)	0.498 (0.082, 3.006) 0.4468	
No	274	66 (24.1%)	208 (75.9%)	25.82 (20.14, N.A.)	274	64 (23.4%)	210 (76.6%)	8.84 (7.89, 14.98)	0.577 (0.396, 0.841) 0.0042	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.2 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Anorexia (Appetite) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.3642
Positive	232	52 (22.4%)	180 (77.6%)	25.82 (20.14, N.A.)	219	45 (20.5%)	174 (79.5%)	8.21 (7.89, N.A.)	0.556 (0.356, 0.868) 0.0098	
Negative	57	17 (29.8%)	40 (70.2%)	16.33 (8.05, N.A.)	78	21 (26.9%)	57 (73.1%)	8.84 (7.72, N.A.)	0.868 (0.438, 1.717) 0.6836	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.2: Subgruppenanalysen für den Endpunkt Fatigue gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.4: Subgroup Time to Definitive Deterioration LCSS: Fatigue (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	89 (29.4%)	214 (70.6%)	20.96 (13.57, N.A.)	302	93 (30.8%)	209 (69.2%)	7.92 (7.36, N.A.)	0.538 (0.391, 0.742) 0.0002	
Age Category:										0.8461
< 65	71	17 (23.9%)	54 (76.1%)	21.91 (8.80, N.A.)	96	27 (28.1%)	69 (71.9%)	7.85 (6.93, N.A.)	0.448 (0.224, 0.896) 0.0231	
>= 65 and <75	154	47 (30.5%)	107 (69.5%)	23.03 (12.62, N.A.)	127	37 (29.1%)	90 (70.9%)	8.15 (7.43, N.A.)	0.518 (0.321, 0.836) 0.0070	
>= 75	78	25 (32.1%)	53 (67.9%)	14.00 (6.93, N.A.)	79	29 (36.7%)	50 (63.3%)	7.43 (4.47, N.A.)	0.689 (0.392, 1.212) 0.1958	
Gender:										0.0319**
Male	234	69 (29.5%)	165 (70.5%)	20.96 (12.62, N.A.)	233	83 (35.6%)	150 (64.4%)	7.72 (7.13, 8.15)	0.488 (0.345, 0.691) <0.0001	
Female	69	20 (29.0%)	49 (71.0%)	17.87 (11.53, N.A.)	69	10 (14.5%)	59 (85.5%)	N.A. (7.46, N.A.)	0.949 (0.406, 2.217) 0.9041	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.4 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Fatigue (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.7434
White	266	76 (28.6%)	190 (71.4%)	20.96 (13.11, N.A.)	250	74 (29.6%)	176 (70.4%)	7.72 (7.26, N.A.)	0.524 (0.370, 0.741) 0.0003	
Asian	26	11 (42.3%)	15 (57.7%)	20.14 (4.24, N.A.)	39	15 (38.5%)	24 (61.5%)	7.92 (7.10, 8.15)	0.554 (0.216, 1.423) 0.2200	
Other	11	2 (18.2%)	9 (81.8%)	N.A. (5.49, N.A.)	13	4 (30.8%)	9 (69.2%)	8.28 (2.30, N.A.)	0.333 (0.028, 3.917) 0.3816	
Region:										0.1175*
North America	32	9 (28.1%)	23 (71.9%)	23.03 (2.79, 23.03)	27	7 (25.9%)	20 (74.1%)	2.83 (0.76, N.A.)	0.477 (0.164, 1.392) 0.1756	
EU	177	49 (27.7%)	128 (72.3%)	20.96 (14.00, N.A.)	175	60 (34.3%)	115 (65.7%)	7.46 (7.16, N.A.)	0.407 (0.268, 0.618) <0.0001	
Asia	26	11 (42.3%)	15 (57.7%)	20.14 (4.24, N.A.)	39	15 (38.5%)	24 (61.5%)	7.92 (7.10, 8.15)	0.554 (0.216, 1.423) 0.2200	
RoW	68	20 (29.4%)	48 (70.6%)	N.A. (7.82, N.A.)	61	11 (18.0%)	50 (82.0%)	N.A. (N.A., N.A.)	1.251 (0.579, 2.701) 0.5693	
ECOG Performance:										0.4003
0	114	35 (30.7%)	79 (69.3%)	21.91 (13.11, N.A.)	128	43 (33.6%)	85 (66.4%)	8.15 (7.36, N.A.)	0.459 (0.284, 0.743) 0.0015	
>= 1	189	54 (28.6%)	135 (71.4%)	20.14 (11.99, N.A.)	174	50 (28.7%)	124 (71.3%)	7.92 (6.93, N.A.)	0.632 (0.409, 0.977) 0.0388	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.4 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Fatigue (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.2625
Epithelioid	236	68 (28.8%)	168 (71.2%)	20.96 (13.11, N.A.)	235	68 (28.9%)	167 (71.1%)	7.92 (7.43, N.A.)	0.577 (0.400, 0.832) 0.0032	
Non-Epithelioid	67	21 (31.3%)	46 (68.7%)	20.14 (9.69, N.A.)	67	25 (37.3%)	42 (62.7%)	8.02 (3.52, 8.15)	0.429 (0.220, 0.836) 0.0129	
Disease Stage at Study Entry:										0.3710
Stage I	12	1 (8.3%)	11 (91.7%)	N.A. (13.11, N.A.)	20	9 (45.0%)	11 (55.0%)	7.85 (1.41, N.A.)	<0.001 (<0.001, N.A.) 0.9954	
Stage II	23	3 (13.0%)	20 (87.0%)	N.A. (8.34, N.A.)	22	6 (27.3%)	16 (72.7%)	N.A. (4.21, N.A.)	0.360 (0.084, 1.531) 0.1664	
Stage III	103	32 (31.1%)	71 (68.9%)	21.91 (12.55, N.A.)	106	31 (29.2%)	75 (70.8%)	8.28 (7.36, N.A.)	0.511 (0.291, 0.898) 0.0196	
Stage IV	160	52 (32.5%)	108 (67.5%)	13.57 (10.78, 25.82)	149	45 (30.2%)	104 (69.8%)	7.36 (6.93, N.A.)	0.633 (0.409, 0.981) 0.0407	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.4 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Fatigue (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.9599
Never	127	34 (26.8%)	93 (73.2%)	20.14 (13.57, N.A.)	122	39 (32.0%)	83 (68.0%)	8.02 (7.23, N.A.)	0.495 (0.295, 0.830) 0.0077	
Former	155	50 (32.3%)	105 (67.7%)	16.33 (11.07, N.A.)	163	50 (30.7%)	113 (69.3%)	7.85 (7.36, N.A.)	0.600 (0.393, 0.916) 0.0181	
Current	18	5 (27.8%)	13 (72.2%)	N.A. (8.28, N.A.)	8	2 (25.0%)	6 (75.0%)	8.28 (5.03, 8.28)	0.533 (0.089, 3.187) 0.4901	
Prior Radiotherapy:										0.4510
Yes	29	6 (20.7%)	23 (79.3%)	20.96 (11.20, N.A.)	28	9 (32.1%)	19 (67.9%)	7.43 (2.10, N.A.)	0.324 (0.083, 1.265) 0.1050	
No	274	83 (30.3%)	191 (69.7%)	20.14 (12.62, N.A.)	274	84 (30.7%)	190 (69.3%)	8.02 (7.36, N.A.)	0.566 (0.407, 0.788) 0.0007	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.4 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Fatigue (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.5108
Positive	232	67 (28.9%)	165 (71.1%)	20.96 (13.57, N.A.)	219	64 (29.2%)	155 (70.8%)	8.02 (7.36, N.A.)	0.544 (0.373, 0.794) 0.0016	
Negative	57	21 (36.8%)	36 (63.2%)	13.11 (9.69, N.A.)	78	27 (34.6%)	51 (65.4%)	7.92 (6.93, N.A.)	0.680 (0.366, 1.263) 0.2219	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.3: Subgruppenanalysen für den Endpunkt Husten gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.6: Subgroup Time to Definitive Deterioration LCSS: Cough (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	59 (19.5%)	244 (80.5%)	27.76 (23.56, N.A.)	302	49 (16.2%)	253 (83.8%)	10.38 (8.02, N.A.)	0.611 (0.401, 0.933) 0.0224	
Age Category:										0.9501
< 65	71	10 (14.1%)	61 (85.9%)	27.76 (16.59, N.A.)	96	11 (11.5%)	85 (88.5%)	N.A. (7.85, N.A.)	0.404 (0.135, 1.207) 0.1045	
>= 65 and <75	154	34 (22.1%)	120 (77.9%)	24.18 (20.21, N.A.)	127	21 (16.5%)	106 (83.5%)	10.38 (7.62, N.A.)	0.664 (0.366, 1.206) 0.1791	
>= 75	78	15 (19.2%)	63 (80.8%)	N.A. (N.A., N.A.)	79	17 (21.5%)	62 (78.5%)	8.84 (8.02, N.A.)	0.667 (0.323, 1.378) 0.2739	
Gender:										0.7165
Male	234	45 (19.2%)	189 (80.8%)	27.76 (27.76, N.A.)	233	38 (16.3%)	195 (83.7%)	10.38 (8.02, N.A.)	0.717 (0.449, 1.144) 0.1630	
Female	69	14 (20.3%)	55 (79.7%)	23.56 (18.76, N.A.)	69	11 (15.9%)	58 (84.1%)	8.84 (8.02, 12.22)	0.325 (0.120, 0.884) 0.0277	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.6 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Cough (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.2990
White	266	49 (18.4%)	217 (81.6%)	27.76 (23.56, N.A.)	250	41 (16.4%)	209 (83.6%)	8.84 (8.02, N.A.)	0.533 (0.336, 0.844) 0.0073	
Asian	26	9 (34.6%)	17 (65.4%)	20.14 (6.93, N.A.)	39	6 (15.4%)	33 (84.6%)	N.A. (N.A., N.A.)	1.422 (0.455, 4.441) 0.5445	
Other	11	1 (9.1%)	10 (90.9%)	N.A. (0.49, N.A.)	13	2 (15.4%)	11 (84.6%)	N.A. (4.53, N.A.)	0.620 (0.055, 6.984) 0.6986	
Region:										0.3112
North America	32	4 (12.5%)	28 (87.5%)	20.27 (8.71, N.A.)	27	2 (7.4%)	25 (92.6%)	N.A. (3.98, N.A.)	0.433 (0.039, 4.793) 0.4951	
EU	177	30 (16.9%)	147 (83.1%)	27.76 (24.18, N.A.)	175	32 (18.3%)	143 (81.7%)	8.84 (7.85, N.A.)	0.414 (0.237, 0.724) 0.0020	
Asia	26	9 (34.6%)	17 (65.4%)	20.14 (6.93, N.A.)	39	6 (15.4%)	33 (84.6%)	N.A. (N.A., N.A.)	1.422 (0.455, 4.441) 0.5445	
RoW	68	16 (23.5%)	52 (76.5%)	23.56 (18.76, N.A.)	61	9 (14.8%)	52 (85.2%)	N.A. (N.A., N.A.)	1.174 (0.498, 2.768) 0.7136	
ECOG Performance:										0.3832
0	114	24 (21.1%)	90 (78.9%)	N.A. (18.76, N.A.)	128	19 (14.8%)	109 (85.2%)	10.38 (8.34, N.A.)	0.682 (0.350, 1.330) 0.2611	
>= 1	189	35 (18.5%)	154 (81.5%)	27.76 (23.56, N.A.)	174	30 (17.2%)	144 (82.8%)	8.02 (7.72, N.A.)	0.570 (0.329, 0.988) 0.0451	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.6 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Cough (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.1094*
Epithelioid	236	38 (16.1%)	198 (83.9%)	27.76 (24.18, N.A.)	235	40 (17.0%)	195 (83.0%)	8.84 (8.02, N.A.)	0.455 (0.275, 0.752) 0.0021	
Non-Epithelioid	67	21 (31.3%)	46 (68.7%)	18.76 (8.97, N.A.)	67	9 (13.4%)	58 (86.6%)	N.A. (N.A., N.A.)	1.338 (0.582, 3.079) 0.4932	
Disease Stage at Study Entry:										0.2090
Stage I	12	2 (16.7%)	10 (83.3%)	N.A. (1.64, N.A.)	20	6 (30.0%)	14 (70.0%)	8.02 (7.72, N.A.)	0.336 (0.065, 1.745) 0.1942	
Stage II	23	5 (21.7%)	18 (78.3%)	N.A. (7.39, N.A.)	22	2 (9.1%)	20 (90.9%)	N.A. (N.A., N.A.)	2.015 (0.382, 10.639) 0.4094	
Stage III	103	20 (19.4%)	83 (80.6%)	27.76 (23.56, N.A.)	106	22 (20.8%)	84 (79.2%)	8.34 (7.62, 8.84)	0.339 (0.161, 0.714) 0.0044	
Stage IV	160	30 (18.8%)	130 (81.3%)	N.A. (20.21, N.A.)	149	19 (12.8%)	130 (87.2%)	12.22 (12.22, N.A.)	0.950 (0.515, 1.751) 0.8693	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.6 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Cough (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.7618
Never	127	27 (21.3%)	100 (78.7%)	24.18 (18.76, N.A.)	122	28 (23.0%)	94 (77.0%)	8.34 (8.02, 10.38)	0.476 (0.261, 0.867) 0.0152	
Former	155	26 (16.8%)	129 (83.2%)	N.A. (23.56, N.A.)	163	21 (12.9%)	142 (87.1%)	N.A. (7.85, N.A.)	0.725 (0.387, 1.355) 0.3134	
Current	18	6 (33.3%)	12 (66.7%)	20.21 (6.60, 27.76)	8	0 (0.0%)	8 (100.0%)	N.A. (N.A., N.A.)	>999.999 (<0.001, N.A.) 0.9962	
Prior Radiotherapy:										0.3303
Yes	29	3 (10.3%)	26 (89.7%)	N.A. (N.A., N.A.)	28	5 (17.9%)	23 (82.1%)	7.72 (7.39, 8.34)	0.326 (0.071, 1.499) 0.1498	
No	274	56 (20.4%)	218 (79.6%)	27.76 (20.27, N.A.)	274	44 (16.1%)	230 (83.9%)	10.38 (8.84, N.A.)	0.659 (0.425, 1.021) 0.0618	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.6 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Cough (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.2666
Positive	232	41 (17.7%)	191 (82.3%)	N.A. (23.56, N.A.)	219	33 (15.1%)	186 (84.9%)	N.A. (8.02, N.A.)	0.619 (0.374, 1.023) 0.0613	
Negative	57	16 (28.1%)	41 (71.9%)	20.27 (9.69, 27.76)	78	15 (19.2%)	63 (80.8%)	8.84 (8.02, N.A.)	0.820 (0.374, 1.796) 0.6196	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.4: Subgruppenanalysen für den Endpunkt Dyspnoe gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.8: Subgroup Time to Definitive Deterioration LCSS: Dyspnea (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	76 (25.1%)	227 (74.9%)	25.82 (20.73, N.A.)	302	60 (19.9%)	242 (80.1%)	12.22 (8.02, N.A.)	0.771 (0.536, 1.109) 0.1605	
Age Category:										0.6772
< 65	71	16 (22.5%)	55 (77.5%)	N.A. (9.69, N.A.)	96	12 (12.5%)	84 (87.5%)	N.A. (7.85, N.A.)	0.992 (0.436, 2.256) 0.9847	
>= 65 and <75	154	40 (26.0%)	114 (74.0%)	25.82 (17.12, N.A.)	127	25 (19.7%)	102 (80.3%)	N.A. (8.15, N.A.)	0.691 (0.402, 1.187) 0.1807	
>= 75	78	20 (25.6%)	58 (74.4%)	N.A. (9.26, N.A.)	79	23 (29.1%)	56 (70.9%)	8.02 (7.66, N.A.)	0.748 (0.401, 1.399) 0.3636	
Gender:										0.5732
Male	234	62 (26.5%)	172 (73.5%)	25.82 (14.52, N.A.)	233	53 (22.7%)	180 (77.3%)	8.34 (8.02, N.A.)	0.776 (0.524, 1.148) 0.2037	
Female	69	14 (20.3%)	55 (79.7%)	N.A. (20.73, N.A.)	69	7 (10.1%)	62 (89.9%)	12.22 (7.69, 12.22)	0.752 (0.278, 2.035) 0.5742	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.8 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Dyspnea (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.4805
White	266	70 (26.3%)	196 (73.7%)	25.36 (17.12, N.A.)	250	44 (17.6%)	206 (82.4%)	12.22 (8.02, N.A.)	0.866 (0.579, 1.295) 0.4827	
Asian	26	6 (23.1%)	20 (76.9%)	N.A. (7.03, N.A.)	39	12 (30.8%)	27 (69.2%)	8.15 (7.13, N.A.)	0.527 (0.180, 1.546) 0.2432	
Other	11	0 (0.0%)	11 (100.0%)	N.A. (N.A., N.A.)	13	4 (30.8%)	9 (69.2%)	8.28 (0.76, N.A.)	<0.001 (<0.001, N.A.) 0.9968	
Region:										0.2973
North America	32	9 (28.1%)	23 (71.9%)	N.A. (2.79, N.A.)	27	3 (11.1%)	24 (88.9%)	7.89 (N.A., N.A.)	1.970 (0.508, 7.637) 0.3267	
EU	177	41 (23.2%)	136 (76.8%)	N.A. (18.46, N.A.)	175	36 (20.6%)	139 (79.4%)	12.22 (7.85, N.A.)	0.598 (0.367, 0.974) 0.0388	
Asia	26	6 (23.1%)	20 (76.9%)	N.A. (7.03, N.A.)	39	12 (30.8%)	27 (69.2%)	8.15 (7.13, N.A.)	0.527 (0.180, 1.546) 0.2432	
RoW	68	20 (29.4%)	48 (70.6%)	25.36 (7.98, N.A.)	61	9 (14.8%)	52 (85.2%)	N.A. (7.66, N.A.)	1.248 (0.545, 2.860) 0.6003	
ECOG Performance:										0.9463
0	114	31 (27.2%)	83 (72.8%)	N.A. (14.00, N.A.)	128	27 (21.1%)	101 (78.9%)	12.22 (8.15, N.A.)	0.689 (0.395, 1.201) 0.1889	
>= 1	189	45 (23.8%)	144 (76.2%)	25.82 (17.12, N.A.)	174	33 (19.0%)	141 (81.0%)	N.A. (7.89, N.A.)	0.826 (0.509, 1.342) 0.4410	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.8 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Dyspnea (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.4220
Epithelioid	236	59 (25.0%)	177 (75.0%)	25.82 (17.12, N.A.)	235	45 (19.1%)	190 (80.9%)	12.22 (8.28, N.A.)	0.756 (0.497, 1.150) 0.1907	
Non-Epithelioid	67	17 (25.4%)	50 (74.6%)	N.A. (12.25, N.A.)	67	15 (22.4%)	52 (77.6%)	8.15 (7.52, N.A.)	0.740 (0.356, 1.541) 0.4217	
Disease Stage at Study Entry:										0.8711
Stage I	12	4 (33.3%)	8 (66.7%)	N.A. (1.64, N.A.)	20	8 (40.0%)	12 (60.0%)	7.85 (3.15, N.A.)	0.765 (0.227, 2.584) 0.6666	
Stage II	23	5 (21.7%)	18 (78.3%)	N.A. (7.92, N.A.)	22	0 (0.0%)	22 (100.0%)	N.A. (N.A., N.A.)	>999.999 (<0.001, N.A.) 0.9966	
Stage III	103	26 (25.2%)	77 (74.8%)	N.A. (20.73, N.A.)	106	23 (21.7%)	83 (78.3%)	8.34 (8.15, N.A.)	0.540 (0.288, 1.013) 0.0550	
Stage IV	160	39 (24.4%)	121 (75.6%)	25.82 (14.00, N.A.)	149	29 (19.5%)	120 (80.5%)	12.22 (7.66, N.A.)	0.820 (0.489, 1.374) 0.4506	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.8 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Dyspnea (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.4596
Never	127	27 (21.3%)	100 (78.7%)	N.A. (17.12, N.A.)	122	23 (18.9%)	99 (81.1%)	12.22 (8.02, N.A.)	0.675 (0.367, 1.241) 0.2060	
Former	155	43 (27.7%)	112 (72.3%)	25.36 (14.52, N.A.)	163	32 (19.6%)	131 (80.4%)	N.A. (7.85, N.A.)	0.898 (0.552, 1.461) 0.6653	
Current	18	6 (33.3%)	12 (66.7%)	13.60 (6.87, N.A.)	8	3 (37.5%)	5 (62.5%)	8.28 (0.72, 8.28)	0.329 (0.074, 1.466) 0.1448	
Prior Radiotherapy:										0.3861
Yes	29	3 (10.3%)	26 (89.7%)	N.A. (14.52, N.A.)	28	4 (14.3%)	24 (85.7%)	8.34 (4.40, N.A.)	0.362 (0.062, 2.118) 0.2593	
No	274	73 (26.6%)	201 (73.4%)	25.82 (18.46, N.A.)	274	56 (20.4%)	218 (79.6%)	12.22 (8.02, N.A.)	0.782 (0.538, 1.135) 0.1958	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.8 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Dyspnea (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.3208
Positive	232	63 (27.2%)	169 (72.8%)	25.36 (14.52, N.A.)	219	39 (17.8%)	180 (82.2%)	N.A. (7.89, N.A.)	0.922 (0.602, 1.411) 0.7073	
Negative	57	11 (19.3%)	46 (80.7%)	N.A. (13.60, N.A.)	78	18 (23.1%)	60 (76.9%)	12.22 (8.02, N.A.)	0.542 (0.244, 1.207) 0.1337	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.5: Subgruppenanalysen für den Endpunkt Schmerz gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.10: Subgroup Time to Definitive Deterioration LCSS: Pain (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	69 (22.8%)	234 (77.2%)	N.A. (19.48, N.A.)	302	59 (19.5%)	243 (80.5%)	12.22 (8.02, N.A.)	0.613 (0.415, 0.903) 0.0133	
Age Category:										0.7888
< 65	71	13 (18.3%)	58 (81.7%)	N.A. (11.73, N.A.)	96	16 (16.7%)	80 (83.3%)	N.A. (7.69, N.A.)	0.388 (0.151, 0.994) 0.0485	
>= 65 and <75	154	39 (25.3%)	115 (74.7%)	23.56 (16.76, N.A.)	127	27 (21.3%)	100 (78.7%)	10.38 (7.62, N.A.)	0.541 (0.312, 0.937) 0.0284	
>= 75	78	17 (21.8%)	61 (78.2%)	N.A. (20.96, N.A.)	79	16 (20.3%)	63 (79.7%)	12.22 (8.02, N.A.)	0.944 (0.463, 1.926) 0.8748	
Gender:										0.0670*
Male	234	48 (20.5%)	186 (79.5%)	N.A. (20.96, N.A.)	233	52 (22.3%)	181 (77.7%)	10.38 (7.69, N.A.)	0.557 (0.362, 0.857) 0.0077	
Female	69	21 (30.4%)	48 (69.6%)	17.05 (11.53, N.A.)	69	7 (10.1%)	62 (89.9%)	12.22 (N.A., N.A.)	0.969 (0.372, 2.520) 0.9479	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.10 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Pain (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.8368
White	266	60 (22.6%)	206 (77.4%)	23.56 (17.05, N.A.)	250	49 (19.6%)	201 (80.4%)	10.38 (7.72, N.A.)	0.551 (0.363, 0.835) 0.0050	
Asian	26	7 (26.9%)	19 (73.1%)	N.A. (7.03, N.A.)	39	8 (20.5%)	31 (79.5%)	N.A. (7.62, N.A.)	1.239 (0.427, 3.598) 0.6933	
Other	11	2 (18.2%)	9 (81.8%)	N.A. (2.79, N.A.)	13	2 (15.4%)	11 (84.6%)	N.A. (4.70, N.A.)	2.950 (0.191, 45.568) 0.4387	
Region:										0.3230
North America	32	5 (15.6%)	27 (84.4%)	N.A. (8.08, N.A.)	27	4 (14.8%)	23 (85.2%)	N.A. (2.83, N.A.)	0.509 (0.112, 2.307) 0.3811	
EU	177	36 (20.3%)	141 (79.7%)	N.A. (19.48, N.A.)	175	37 (21.1%)	138 (78.9%)	10.38 (7.72, N.A.)	0.447 (0.268, 0.746) 0.0021	
Asia	26	7 (26.9%)	19 (73.1%)	N.A. (7.03, N.A.)	39	8 (20.5%)	31 (79.5%)	N.A. (7.62, N.A.)	1.239 (0.427, 3.598) 0.6933	
RoW	68	21 (30.9%)	47 (69.1%)	16.36 (8.97, N.A.)	61	10 (16.4%)	51 (83.6%)	N.A. (7.56, N.A.)	1.046 (0.460, 2.377) 0.9146	
ECOG Performance:										0.7215
0	114	26 (22.8%)	88 (77.2%)	N.A. (17.87, N.A.)	128	25 (19.5%)	103 (80.5%)	12.22 (10.38, N.A.)	0.592 (0.325, 1.080) 0.0876	
>= 1	189	43 (22.8%)	146 (77.2%)	23.56 (16.76, N.A.)	174	34 (19.5%)	140 (80.5%)	N.A. (7.56, N.A.)	0.611 (0.369, 1.013) 0.0559	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.10 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Pain (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.3151
Epithelioid	236	55 (23.3%)	181 (76.7%)	23.56 (17.87, N.A.)	235	45 (19.1%)	190 (80.9%)	12.22 (8.02, N.A.)	0.634 (0.409, 0.982) 0.0412	
Non-Epithelioid	67	14 (20.9%)	53 (79.1%)	N.A. (11.83, N.A.)	67	14 (20.9%)	53 (79.1%)	N.A. (7.29, N.A.)	0.520 (0.228, 1.185) 0.1197	
Disease Stage at Study Entry:										0.4109
Stage I	12	2 (16.7%)	10 (83.3%)	N.A. (1.64, N.A.)	20	6 (30.0%)	14 (70.0%)	10.38 (7.43, N.A.)	0.466 (0.091, 2.394) 0.3607	
Stage II	23	1 (4.3%)	22 (95.7%)	N.A. (11.83, N.A.)	22	2 (9.1%)	20 (90.9%)	N.A. (7.29, N.A.)	0.312 (0.025, 3.832) 0.3630	
Stage III	103	24 (23.3%)	79 (76.7%)	N.A. (22.05, N.A.)	106	23 (21.7%)	83 (78.3%)	N.A. (7.62, N.A.)	0.497 (0.255, 0.966) 0.0391	
Stage IV	160	41 (25.6%)	119 (74.4%)	19.48 (12.62, N.A.)	149	27 (18.1%)	122 (81.9%)	12.22 (7.59, N.A.)	0.837 (0.489, 1.433) 0.5159	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.10 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Pain (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.9037
Never	127	28 (22.0%)	99 (78.0%)	N.A. (16.76, N.A.)	122	25 (20.5%)	97 (79.5%)	12.22 (8.02, N.A.)	0.652 (0.360, 1.182) 0.1588	
Former	155	35 (22.6%)	120 (77.4%)	23.56 (19.48, N.A.)	163	31 (19.0%)	132 (81.0%)	N.A. (7.69, N.A.)	0.618 (0.362, 1.054) 0.0773	
Current	18	6 (33.3%)	12 (66.7%)	N.A. (7.98, N.A.)	8	1 (12.5%)	7 (87.5%)	N.A. (0.72, N.A.)	1.102 (0.109, 11.128) 0.9345	
Prior Radiotherapy:										0.7284
Yes	29	7 (24.1%)	22 (75.9%)	20.96 (9.63, N.A.)	28	4 (14.3%)	24 (85.7%)	N.A. (4.70, N.A.)	0.510 (0.112, 2.320) 0.3839	
No	274	62 (22.6%)	212 (77.4%)	N.A. (19.48, N.A.)	274	55 (20.1%)	219 (79.9%)	12.22 (8.02, N.A.)	0.608 (0.407, 0.908) 0.0149	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.10 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Pain (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.3208
Positive	232	52 (22.4%)	180 (77.6%)	23.56 (17.05, N.A.)	219	42 (19.2%)	177 (80.8%)	N.A. (7.72, N.A.)	0.538 (0.338, 0.857) 0.0090	
Negative	57	15 (26.3%)	42 (73.7%)	N.A. (8.31, N.A.)	78	14 (17.9%)	64 (82.1%)	12.22 (8.02, N.A.)	1.108 (0.519, 2.364) 0.7917	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.6: Subgruppenanalysen für den Endpunkt Symptombelastung gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.12: Subgroup Time to Definitive Deterioration LCSS: Symptom Distress (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	70 (23.1%)	233 (76.9%)	25.82 (20.27, N.A.)	302	69 (22.8%)	233 (77.2%)	12.22 (8.02, N.A.)	0.616 (0.429, 0.884) 0.0085	
Age Category:										0.9200
< 65	71	12 (16.9%)	59 (83.1%)	N.A. (13.57, N.A.)	96	17 (17.7%)	79 (82.3%)	N.A. (7.43, N.A.)	0.549 (0.242, 1.244) 0.1507	
>= 65 and <75	154	40 (26.0%)	114 (74.0%)	25.82 (14.52, N.A.)	127	29 (22.8%)	98 (77.2%)	8.80 (7.56, N.A.)	0.590 (0.349, 0.997) 0.0487	
>= 75	78	18 (23.1%)	60 (76.9%)	N.A. (10.74, N.A.)	79	23 (29.1%)	56 (70.9%)	12.22 (7.16, N.A.)	0.727 (0.384, 1.376) 0.3273	
Gender:										0.3313
Male	234	53 (22.6%)	181 (77.4%)	25.82 (20.27, N.A.)	233	58 (24.9%)	175 (75.1%)	8.80 (7.66, N.A.)	0.573 (0.383, 0.858) 0.0068	
Female	69	17 (24.6%)	52 (75.4%)	N.A. (12.71, N.A.)	69	11 (15.9%)	58 (84.1%)	12.22 (7.72, 12.22)	0.874 (0.379, 2.016) 0.7527	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.12 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Symptom Distress (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.4114
White	266	62 (23.3%)	204 (76.7%)	25.82 (17.05, N.A.)	250	49 (19.6%)	201 (80.4%)	12.22 (8.02, N.A.)	0.665 (0.444, 0.996) 0.0477	
Asian	26	7 (26.9%)	19 (73.1%)	N.A. (4.24, N.A.)	39	15 (38.5%)	24 (61.5%)	8.15 (5.91, N.A.)	0.808 (0.320, 2.036) 0.6504	
Other	11	1 (9.1%)	10 (90.9%)	N.A. (11.99, N.A.)	13	5 (38.5%)	8 (61.5%)	N.A. (1.61, N.A.)	<0.001 (<0.001, N.A.) 0.9964	
Region:										0.8789
North America	32	5 (15.6%)	27 (84.4%)	N.A. (20.27, N.A.)	27	4 (14.8%)	23 (85.2%)	N.A. (2.33, N.A.)	0.595 (0.148, 2.397) 0.4649	
EU	177	45 (25.4%)	132 (74.6%)	25.82 (13.60, N.A.)	175	38 (21.7%)	137 (78.3%)	12.22 (8.02, N.A.)	0.635 (0.398, 1.015) 0.0577	
Asia	26	7 (26.9%)	19 (73.1%)	N.A. (4.24, N.A.)	39	15 (38.5%)	24 (61.5%)	8.15 (5.91, N.A.)	0.808 (0.320, 2.036) 0.6504	
RoW	68	13 (19.1%)	55 (80.9%)	N.A. (13.57, N.A.)	61	12 (19.7%)	49 (80.3%)	N.A. (7.56, N.A.)	0.642 (0.281, 1.465) 0.2924	
ECOG Performance:										0.4978
0	114	30 (26.3%)	84 (73.7%)	N.A. (13.60, N.A.)	128	30 (23.4%)	98 (76.6%)	12.22 (7.72, N.A.)	0.595 (0.345, 1.028) 0.0627	
>= 1	189	40 (21.2%)	149 (78.8%)	N.A. (17.05, N.A.)	174	39 (22.4%)	135 (77.6%)	N.A. (7.56, N.A.)	0.639 (0.396, 1.032) 0.0671	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.12 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Symptom Distress (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.5891
Epithelioid	236	50 (21.2%)	186 (78.8%)	25.82 (21.91, N.A.)	235	54 (23.0%)	181 (77.0%)	12.22 (8.02, N.A.)	0.515 (0.337, 0.788) 0.0022	
Non-Epithelioid	67	20 (29.9%)	47 (70.1%)	20.27 (5.55, N.A.)	67	15 (22.4%)	52 (77.6%)	8.15 (7.43, N.A.)	0.953 (0.478, 1.904) 0.8925	
Disease Stage at Study Entry:										0.5060
Stage I	12	4 (33.3%)	8 (66.7%)	9.89 (1.64, N.A.)	20	5 (25.0%)	15 (75.0%)	N.A. (4.70, N.A.)	1.244 (0.315, 4.918) 0.7554	
Stage II	23	3 (13.0%)	20 (87.0%)	N.A. (11.83, N.A.)	22	2 (9.1%)	20 (90.9%)	N.A. (N.A., N.A.)	1.270 (0.202, 8.006) 0.7988	
Stage III	103	22 (21.4%)	81 (78.6%)	N.A. (21.91, N.A.)	106	24 (22.6%)	82 (77.4%)	8.80 (7.72, N.A.)	0.433 (0.221, 0.848) 0.0146	
Stage IV	160	38 (23.8%)	122 (76.3%)	25.82 (13.57, N.A.)	149	37 (24.8%)	112 (75.2%)	12.22 (7.52, N.A.)	0.610 (0.373, 0.998) 0.0492	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.12 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Symptom Distress (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.5456
Never	127	31 (24.4%)	96 (75.6%)	22.05 (13.57, N.A.)	122	27 (22.1%)	95 (77.9%)	12.22 (7.72, N.A.)	0.695 (0.395, 1.224) 0.2077	
Former	155	34 (21.9%)	121 (78.1%)	25.82 (21.91, N.A.)	163	40 (24.5%)	123 (75.5%)	8.80 (7.62, N.A.)	0.575 (0.353, 0.936) 0.0260	
Current	18	5 (27.8%)	13 (72.2%)	13.60 (6.60, N.A.)	8	1 (12.5%)	7 (87.5%)	N.A. (0.72, N.A.)	0.814 (0.080, 8.238) 0.8616	
Prior Radiotherapy:										0.0893*
Yes	29	8 (27.6%)	21 (72.4%)	12.71 (4.44, N.A.)	28	2 (7.1%)	26 (92.9%)	N.A. (7.39, N.A.)	1.701 (0.307, 9.419) 0.5432	
No	274	62 (22.6%)	212 (77.4%)	N.A. (21.91, N.A.)	274	67 (24.5%)	207 (75.5%)	8.80 (7.72, N.A.)	0.574 (0.395, 0.835) 0.0036	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.12 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Symptom Distress (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.3425
Positive	232	51 (22.0%)	181 (78.0%)	25.82 (21.91, N.A.)	219	48 (21.9%)	171 (78.1%)	N.A. (7.72, N.A.)	0.554 (0.358, 0.855) 0.0077	
Negative	57	15 (26.3%)	42 (73.7%)	N.A. (9.89, N.A.)	78	18 (23.1%)	60 (76.9%)	12.22 (8.02, N.A.)	0.941 (0.455, 1.949) 0.8708	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.7: Subgruppenanalysen für den Endpunkt Aktivitätsbeeinträchtigung gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.14: Subgroup Time to Definitive Deterioration LCSS: Interference with Activity Level (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	75 (24.8%)	228 (75.2%)	25.82 (15.18, N.A.)	302	72 (23.8%)	230 (76.2%)	8.15 (7.66, N.A.)	0.592 (0.415, 0.844) 0.0038	
Age Category:										0.6882
< 65	71	13 (18.3%)	58 (81.7%)	N.A. (12.19, N.A.)	96	14 (14.6%)	82 (85.4%)	N.A. (7.62, N.A.)	0.682 (0.294, 1.584) 0.3736	
>= 65 and <75	154	45 (29.2%)	109 (70.8%)	25.82 (12.62, N.A.)	127	30 (23.6%)	97 (76.4%)	8.15 (7.52, N.A.)	0.624 (0.377, 1.033) 0.0666	
>= 75	78	17 (21.8%)	61 (78.2%)	24.90 (9.92, N.A.)	79	28 (35.4%)	51 (64.6%)	8.02 (5.62, 12.22)	0.510 (0.270, 0.964) 0.0383	
Gender:										0.6396
Male	234	58 (24.8%)	176 (75.2%)	25.82 (15.18, N.A.)	233	60 (25.8%)	173 (74.2%)	8.02 (7.62, N.A.)	0.614 (0.417, 0.905) 0.0138	
Female	69	17 (24.6%)	52 (75.4%)	16.92 (12.71, N.A.)	69	12 (17.4%)	57 (82.6%)	8.80 (7.52, 12.22)	0.546 (0.224, 1.331) 0.1830	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.14 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Interference with Activity Level (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.4751
White	266	65 (24.4%)	201 (75.6%)	25.82 (13.60, N.A.)	250	54 (21.6%)	196 (78.4%)	8.80 (7.72, N.A.)	0.633 (0.429, 0.934) 0.0214	
Asian	26	7 (26.9%)	19 (73.1%)	N.A. (9.72, N.A.)	39	15 (38.5%)	24 (61.5%)	8.02 (5.91, N.A.)	0.381 (0.133, 1.091) 0.0721	
Other	11	3 (27.3%)	8 (72.7%)	24.90 (0.49, N.A.)	13	3 (23.1%)	10 (76.9%)	N.A. (4.67, N.A.)	2.643 (0.300, 23.315) 0.3815	
Region:										0.5676
North America	32	8 (25.0%)	24 (75.0%)	N.A. (3.22, N.A.)	27	3 (11.1%)	24 (88.9%)	N.A. (6.05, N.A.)	1.283 (0.318, 5.175) 0.7258	
EU	177	46 (26.0%)	131 (74.0%)	24.90 (13.60, N.A.)	175	44 (25.1%)	131 (74.9%)	8.80 (7.52, N.A.)	0.555 (0.355, 0.870) 0.0102	
Asia	26	7 (26.9%)	19 (73.1%)	N.A. (9.72, N.A.)	39	15 (38.5%)	24 (61.5%)	8.02 (5.91, N.A.)	0.381 (0.133, 1.091) 0.0721	
RoW	68	14 (20.6%)	54 (79.4%)	N.A. (12.19, N.A.)	61	10 (16.4%)	51 (83.6%)	N.A. (7.62, N.A.)	0.877 (0.357, 2.153) 0.7742	
ECOG Performance:										0.2371
0	114	33 (28.9%)	81 (71.1%)	N.A. (11.60, N.A.)	128	29 (22.7%)	99 (77.3%)	12.22 (7.85, N.A.)	0.680 (0.397, 1.163) 0.1589	
>= 1	189	42 (22.2%)	147 (77.8%)	25.82 (16.33, N.A.)	174	43 (24.7%)	131 (75.3%)	8.02 (7.43, 8.80)	0.532 (0.330, 0.858) 0.0097	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.14 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Interference with Activity Level (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.0552*
Epithelioid	236	62 (26.3%)	174 (73.7%)	24.90 (13.60, N.A.)	235	53 (22.6%)	182 (77.4%)	8.80 (7.72, N.A.)	0.682 (0.457, 1.018) 0.0609	
Non-Epithelioid	67	13 (19.4%)	54 (80.6%)	N.A. (12.19, N.A.)	67	19 (28.4%)	48 (71.6%)	7.52 (4.93, 8.15)	0.368 (0.169, 0.805) 0.0123	
Disease Stage at Study Entry:										0.6963
Stage I	12	5 (41.7%)	7 (58.3%)	12.19 (1.64, 12.19)	20	7 (35.0%)	13 (65.0%)	8.02 (7.43, N.A.)	1.306 (0.386, 4.420) 0.6678	
Stage II	23	3 (13.0%)	20 (87.0%)	N.A. (9.72, N.A.)	22	3 (13.6%)	19 (86.4%)	N.A. (7.29, N.A.)	0.784 (0.156, 3.942) 0.7674	
Stage III	103	28 (27.2%)	75 (72.8%)	N.A. (16.33, N.A.)	106	28 (26.4%)	78 (73.6%)	8.15 (7.43, N.A.)	0.580 (0.323, 1.041) 0.0680	
Stage IV	160	37 (23.1%)	123 (76.9%)	25.82 (12.45, N.A.)	149	34 (22.8%)	115 (77.2%)	8.02 (7.52, N.A.)	0.526 (0.310, 0.892) 0.0172	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.14 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Interference with Activity Level (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.4113
Never	127	28 (22.0%)	99 (78.0%)	N.A. (15.18, N.A.)	122	34 (27.9%)	88 (72.1%)	8.02 (7.46, N.A.)	0.478 (0.275, 0.830) 0.0088	
Former	155	43 (27.7%)	112 (72.3%)	24.90 (11.07, N.A.)	163	36 (22.1%)	127 (77.9%)	8.15 (7.62, N.A.)	0.735 (0.455, 1.188) 0.2093	
Current	18	4 (22.2%)	14 (77.8%)	N.A. (13.60, N.A.)	8	1 (12.5%)	7 (87.5%)	N.A. (0.72, N.A.)	1.018 (0.105, 9.861) 0.9879	
Prior Radiotherapy:										0.7341
Yes	29	6 (20.7%)	23 (79.3%)	12.71 (9.72, N.A.)	28	5 (17.9%)	23 (82.1%)	7.72 (4.70, 7.72)	0.425 (0.091, 1.989) 0.2771	
No	274	69 (25.2%)	205 (74.8%)	25.82 (16.33, N.A.)	274	67 (24.5%)	207 (75.5%)	8.80 (7.66, N.A.)	0.602 (0.418, 0.868) 0.0065	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.14 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Interference with Activity Level (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.3710
Positive	232	54 (23.3%)	178 (76.7%)	25.82 (15.18, N.A.)	219	50 (22.8%)	169 (77.2%)	8.15 (7.62, N.A.)	0.558 (0.365, 0.854) 0.0072	
Negative	57	17 (29.8%)	40 (70.2%)	16.33 (8.31, N.A.)	78	20 (25.6%)	58 (74.4%)	12.22 (7.43, N.A.)	0.850 (0.428, 1.689) 0.6427	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.8: Subgruppenanalysen für den Endpunkt allgemeine gesundheitsbezogene Lebensqualität gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.16: Subgroup Time to Definitive Deterioration LCSS: Global HRQoL (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	80 (26.4%)	223 (73.6%)	25.82 (17.05, N.A.)	302	76 (25.2%)	226 (74.8%)	8.15 (7.85, N.A.)	0.621 (0.441, 0.875) 0.0064	
Age Category:										0.5443
< 65	71	15 (21.1%)	56 (78.9%)	N.A. (9.69, N.A.)	96	13 (13.5%)	83 (86.5%)	N.A. (7.85, N.A.)	1.010 (0.460, 2.219) 0.9800	
>= 65 and <75	154	44 (28.6%)	110 (71.4%)	25.82 (12.62, N.A.)	127	36 (28.3%)	91 (71.7%)	8.15 (7.39, N.A.)	0.525 (0.322, 0.856) 0.0097	
>= 75	78	21 (26.9%)	57 (73.1%)	20.96 (13.83, N.A.)	79	27 (34.2%)	52 (65.8%)	8.02 (7.16, N.A.)	0.572 (0.310, 1.056) 0.0744	
Gender:										0.0218**
Male	234	57 (24.4%)	177 (75.6%)	25.82 (20.96, N.A.)	233	66 (28.3%)	167 (71.7%)	8.02 (7.62, N.A.)	0.531 (0.362, 0.781) 0.0013	
Female	69	23 (33.3%)	46 (66.7%)	17.05 (9.69, N.A.)	69	10 (14.5%)	59 (85.5%)	12.22 (8.08, 12.22)	1.232 (0.553, 2.746) 0.6094	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.16 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Global HRQoL (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.6550
White	266	70 (26.3%)	196 (73.7%)	23.46 (16.36, N.A.)	250	56 (22.4%)	194 (77.6%)	12.22 (8.02, N.A.)	0.694 (0.476, 1.013) 0.0584	
Asian	26	9 (34.6%)	17 (65.4%)	13.83 (9.69, N.A.)	39	17 (43.6%)	22 (56.4%)	7.62 (5.32, 8.15)	0.397 (0.149, 1.059) 0.0650	
Other	11	1 (9.1%)	10 (90.9%)	N.A. (2.37, N.A.)	13	3 (23.1%)	10 (76.9%)	N.A. (4.70, N.A.)	0.421 (0.037, 4.750) 0.4842	
Region:										0.8329
North America	32	7 (21.9%)	25 (78.1%)	N.A. (8.71, N.A.)	27	6 (22.2%)	21 (77.8%)	6.05 (3.98, N.A.)	0.579 (0.175, 1.913) 0.3700	
EU	177	47 (26.6%)	130 (73.4%)	23.46 (15.77, N.A.)	175	41 (23.4%)	134 (76.6%)	12.22 (8.02, N.A.)	0.629 (0.398, 0.994) 0.0470	
Asia	26	9 (34.6%)	17 (65.4%)	13.83 (9.69, N.A.)	39	17 (43.6%)	22 (56.4%)	7.62 (5.32, 8.15)	0.397 (0.149, 1.059) 0.0650	
RoW	68	17 (25.0%)	51 (75.0%)	N.A. (12.62, N.A.)	61	12 (19.7%)	49 (80.3%)	N.A. (7.56, N.A.)	0.991 (0.461, 2.129) 0.9814	
ECOG Performance:										0.5389
0	114	32 (28.1%)	82 (71.9%)	23.46 (11.60, N.A.)	128	36 (28.1%)	92 (71.9%)	12.22 (7.62, N.A.)	0.512 (0.305, 0.859) 0.0113	
>= 1	189	48 (25.4%)	141 (74.6%)	25.82 (13.83, N.A.)	174	40 (23.0%)	134 (77.0%)	8.02 (8.02, N.A.)	0.735 (0.464, 1.164) 0.1891	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.16 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Global HRQoL (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.0270**
Epithelioid	236	65 (27.5%)	171 (72.5%)	23.46 (15.77, N.A.)	235	54 (23.0%)	181 (77.0%)	12.22 (7.85, N.A.)	0.725 (0.490, 1.075) 0.1094	
Non-Epithelioid	67	15 (22.4%)	52 (77.6%)	N.A. (11.07, N.A.)	67	22 (32.8%)	45 (67.2%)	8.02 (3.98, 8.15)	0.372 (0.182, 0.759) 0.0066	
Disease Stage at Study Entry:										0.1566*
Stage I	12	3 (25.0%)	9 (75.0%)	N.A. (1.64, N.A.)	20	4 (20.0%)	16 (80.0%)	N.A. (7.85, N.A.)	1.316 (0.286, 6.063) 0.7244	
Stage II	23	2 (8.7%)	21 (91.3%)	N.A. (N.A., N.A.)	22	2 (9.1%)	20 (90.9%)	N.A. (N.A., N.A.)	0.910 (0.126, 6.582) 0.9256	
Stage III	103	23 (22.3%)	80 (77.7%)	N.A. (22.05, N.A.)	106	30 (28.3%)	76 (71.7%)	N.A. (6.60, N.A.)	0.397 (0.212, 0.744) 0.0039	
Stage IV	160	49 (30.6%)	111 (69.4%)	16.36 (10.78, 25.82)	149	39 (26.2%)	110 (73.8%)	7.66 (7.52, N.A.)	0.693 (0.437, 1.099) 0.1190	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.16 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Global HRQoL (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.8763
Never	127	32 (25.2%)	95 (74.8%)	N.A. (13.83, N.A.)	122	32 (26.2%)	90 (73.8%)	8.08 (8.02, N.A.)	0.630 (0.369, 1.073) 0.0892	
Former	155	43 (27.7%)	112 (72.3%)	25.82 (11.60, N.A.)	163	40 (24.5%)	123 (75.5%)	8.15 (7.62, N.A.)	0.694 (0.436, 1.106) 0.1242	
Current	18	5 (27.8%)	13 (72.2%)	23.46 (6.60, N.A.)	8	2 (25.0%)	6 (75.0%)	N.A. (1.64, N.A.)	0.385 (0.062, 2.380) 0.3043	
Prior Radiotherapy:										0.3269
Yes	29	7 (24.1%)	22 (75.9%)	20.96 (2.37, N.A.)	28	4 (14.3%)	24 (85.7%)	N.A. (4.70, N.A.)	0.962 (0.240, 3.862) 0.9569	
No	274	73 (26.6%)	201 (73.4%)	25.82 (17.05, N.A.)	274	72 (26.3%)	202 (73.7%)	8.15 (7.85, N.A.)	0.610 (0.429, 0.868) 0.0060	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.16 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Global HRQoL (reversed) (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.0191**
Positive	232	53 (22.8%)	179 (77.2%)	25.82 (17.05, N.A.)	219	55 (25.1%)	164 (74.9%)	8.08 (7.62, N.A.)	0.502 (0.330, 0.764) 0.0013	
Negative	57	23 (40.4%)	34 (59.6%)	10.97 (2.79, N.A.)	78	18 (23.1%)	60 (76.9%)	12.22 (8.02, N.A.)	1.405 (0.741, 2.667) 0.2978	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.9: Subgruppenanalysen für den Endpunkt Index-Wert der krankheitsbedingten Symptome gemäß LCSS-Meso (MID 15 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.18: Subgroup Time to Definitive Deterioration LCSS: ASBI (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	64 (21.1%)	239 (78.9%)	N.A. (22.18, N.A.)	302	59 (19.5%)	243 (80.5%)	12.22 (8.02, N.A.)	0.577 (0.389, 0.856) 0.0063	
Age Category:										0.5324
< 65	71	17 (23.9%)	54 (76.1%)	17.87 (9.69, N.A.)	96	14 (14.6%)	82 (85.4%)	N.A. (7.85, N.A.)	0.766 (0.338, 1.734) 0.5221	
>= 65 and <75	154	33 (21.4%)	121 (78.6%)	25.82 (22.18, N.A.)	127	25 (19.7%)	102 (80.3%)	N.A. (7.69, N.A.)	0.484 (0.268, 0.874) 0.0160	
>= 75	78	14 (17.9%)	64 (82.1%)	N.A. (N.A., N.A.)	79	20 (25.3%)	59 (74.7%)	8.02 (7.52, N.A.)	0.597 (0.294, 1.212) 0.1534	
Gender:										0.2759
Male	234	48 (20.5%)	186 (79.5%)	N.A. (23.03, N.A.)	233	51 (21.9%)	182 (78.1%)	N.A. (7.85, N.A.)	0.537 (0.348, 0.829) 0.0050	
Female	69	16 (23.2%)	53 (76.8%)	N.A. (17.05, N.A.)	69	8 (11.6%)	61 (88.4%)	12.22 (7.89, 12.22)	0.805 (0.311, 2.087) 0.6559	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.18 (CONT.): Subgroup Time to Definitive Deterioration LCSS: ASBI (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.7750
White	266	55 (20.7%)	211 (79.3%)	25.82 (22.18, N.A.)	250	47 (18.8%)	203 (81.2%)	12.22 (7.85, N.A.)	0.541 (0.352, 0.832) 0.0051	
Asian	26	9 (34.6%)	17 (65.4%)	N.A. (4.24, N.A.)	39	10 (25.6%)	29 (74.4%)	8.02 (7.52, N.A.)	0.848 (0.310, 2.324) 0.7489	
Other	11	0 (0.0%)	11 (100.0%)	N.A. (N.A., N.A.)	13	2 (15.4%)	11 (84.6%)	N.A. (2.92, N.A.)	<0.001 (<0.001, N.A.) 0.9977	
Region:										0.5966
North America	32	7 (21.9%)	25 (78.1%)	23.03 (8.71, 23.03)	27	6 (22.2%)	21 (77.8%)	7.89 (2.33, 7.89)	0.371 (0.099, 1.390) 0.1412	
EU	177	34 (19.2%)	143 (80.8%)	N.A. (17.87, N.A.)	175	34 (19.4%)	141 (80.6%)	12.22 (7.85, N.A.)	0.418 (0.244, 0.714) 0.0014	
Asia	26	9 (34.6%)	17 (65.4%)	N.A. (4.24, N.A.)	39	10 (25.6%)	29 (74.4%)	8.02 (7.52, N.A.)	0.848 (0.310, 2.324) 0.7489	
RoW	68	14 (20.6%)	54 (79.4%)	N.A. (16.36, N.A.)	61	9 (14.8%)	52 (85.2%)	N.A. (N.A., N.A.)	1.187 (0.502, 2.805) 0.6968	
ECOG Performance:										0.6698
0	114	26 (22.8%)	88 (77.2%)	N.A. (16.59, N.A.)	128	25 (19.5%)	103 (80.5%)	12.22 (7.85, N.A.)	0.515 (0.279, 0.949) 0.0335	
>= 1	189	38 (20.1%)	151 (79.9%)	N.A. (22.18, N.A.)	174	34 (19.5%)	140 (80.5%)	8.02 (7.72, N.A.)	0.611 (0.365, 1.023) 0.0608	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.18 (CONT.): Subgroup Time to Definitive Deterioration LCSS: ASBI (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.3606
Epithelioid	236	51 (21.6%)	185 (78.4%)	N.A. (22.18, N.A.)	235	46 (19.6%)	189 (80.4%)	12.22 (7.85, N.A.)	0.606 (0.390, 0.942) 0.0260	
Non-Epithelioid	67	13 (19.4%)	54 (80.6%)	N.A. (13.04, N.A.)	67	13 (19.4%)	54 (80.6%)	8.02 (7.89, N.A.)	0.438 (0.180, 1.065) 0.0686	
Disease Stage at Study Entry:										0.2981
Stage I	12	1 (8.3%)	11 (91.7%)	N.A. (1.64, N.A.)	20	7 (35.0%)	13 (65.0%)	7.85 (7.43, N.A.)	0.200 (0.024, 1.639) 0.1338	
Stage II	23	3 (13.0%)	20 (87.0%)	N.A. (11.83, N.A.)	22	0 (0.0%)	22 (100.0%)	N.A. (N.A., N.A.)	>999.999 (<0.001, N.A.) 0.9975	
Stage III	103	21 (20.4%)	82 (79.6%)	N.A. (N.A., N.A.)	106	24 (22.6%)	82 (77.4%)	N.A. (7.69, N.A.)	0.437 (0.223, 0.856) 0.0158	
Stage IV	160	36 (22.5%)	124 (77.5%)	23.03 (16.36, N.A.)	149	27 (18.1%)	122 (81.9%)	12.22 (7.59, N.A.)	0.675 (0.386, 1.180) 0.1681	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.18 (CONT.): Subgroup Time to Definitive Deterioration LCSS: ASBI (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.3502
Never	127	26 (20.5%)	101 (79.5%)	N.A. (17.87, N.A.)	122	28 (23.0%)	94 (77.0%)	12.22 (8.02, N.A.)	0.545 (0.302, 0.983) 0.0436	
Former	155	35 (22.6%)	120 (77.4%)	25.82 (14.52, N.A.)	163	27 (16.6%)	136 (83.4%)	N.A. (7.72, N.A.)	0.665 (0.381, 1.163) 0.1526	
Current	18	3 (16.7%)	15 (83.3%)	N.A. (8.28, N.A.)	8	2 (25.0%)	6 (75.0%)	N.A. (0.76, N.A.)	0.423 (0.066, 2.694) 0.3622	
Prior Radiotherapy:										0.9138
Yes	29	3 (10.3%)	26 (89.7%)	N.A. (11.20, N.A.)	28	3 (10.7%)	25 (89.3%)	7.72 (7.69, N.A.)	0.150 (0.013, 1.686) 0.1244	
No	274	61 (22.3%)	213 (77.7%)	N.A. (22.18, N.A.)	274	56 (20.4%)	218 (79.6%)	12.22 (8.02, N.A.)	0.588 (0.394, 0.877) 0.0092	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.18 (CONT.): Subgroup Time to Definitive Deterioration LCSS: ASBI (MID=15) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.0953*
Positive	232	47 (20.3%)	185 (79.7%)	N.A. (17.05, N.A.)	219	44 (20.1%)	175 (79.9%)	8.15 (7.72, N.A.)	0.455 (0.284, 0.727) 0.0010	
Negative	57	16 (28.1%)	41 (71.9%)	23.03 (17.87, N.A.)	78	14 (17.9%)	64 (82.1%)	12.22 (8.02, N.A.)	1.156 (0.533, 2.508) 0.7138	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.10: Subgruppenanalysen für den Endpunkt Index-Wert der gesundheitsbezogenen Lebensqualität gemäß LCSS-Meso (MID 45 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.20: Subgroup Time to Definitive Deterioration LCSS: Three-item Index (MID=45) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	74 (24.4%)	229 (75.6%)	25.82 (17.05, N.A.)	302	65 (21.5%)	237 (78.5%)	12.22 (8.02, N.A.)	0.640 (0.444, 0.921) 0.0163	
Age Category:										0.8010
< 65	71	14 (19.7%)	57 (80.3%)	N.A. (11.01, N.A.)	96	13 (13.5%)	83 (86.5%)	N.A. (7.85, N.A.)	1.006 (0.456, 2.221) 0.9883	
>= 65 and <75	154	42 (27.3%)	112 (72.7%)	22.05 (12.71, N.A.)	127	29 (22.8%)	98 (77.2%)	N.A. (7.56, N.A.)	0.515 (0.302, 0.881) 0.0153	
>= 75	78	18 (23.1%)	60 (76.9%)	N.A. (9.92, N.A.)	79	23 (29.1%)	56 (70.9%)	8.08 (7.66, N.A.)	0.699 (0.370, 1.321) 0.2703	
Gender:										0.1832*
Male	234	52 (22.2%)	182 (77.8%)	25.82 (22.05, N.A.)	233	53 (22.7%)	180 (77.3%)	N.A. (7.85, N.A.)	0.569 (0.375, 0.865) 0.0083	
Female	69	22 (31.9%)	47 (68.1%)	17.05 (11.73, N.A.)	69	12 (17.4%)	57 (82.6%)	12.22 (8.08, 12.22)	0.941 (0.436, 2.031) 0.8761	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.20 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Three-item Index (MID=45) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.5436
White	266	65 (24.4%)	201 (75.6%)	23.03 (14.29, N.A.)	250	47 (18.8%)	203 (81.2%)	12.22 (8.02, N.A.)	0.709 (0.472, 1.064) 0.0971	
Asian	26	7 (26.9%)	19 (73.1%)	N.A. (4.24, N.A.)	39	14 (35.9%)	25 (64.1%)	8.02 (7.13, N.A.)	0.547 (0.202, 1.483) 0.2361	
Other	11	2 (18.2%)	9 (81.8%)	N.A. (4.17, N.A.)	13	4 (30.8%)	9 (69.2%)	N.A. (1.41, N.A.)	0.399 (0.038, 4.228) 0.4453	
Region:										0.6861
North America	32	6 (18.8%)	26 (81.3%)	23.03 (9.26, 23.03)	27	4 (14.8%)	23 (85.2%)	N.A. (2.79, N.A.)	0.476 (0.106, 2.149) 0.3348	
EU	177	46 (26.0%)	131 (74.0%)	22.05 (13.60, N.A.)	175	38 (21.7%)	137 (78.3%)	12.22 (8.02, N.A.)	0.630 (0.395, 1.005) 0.0523	
Asia	26	7 (26.9%)	19 (73.1%)	N.A. (4.24, N.A.)	39	14 (35.9%)	25 (64.1%)	8.02 (7.13, N.A.)	0.547 (0.202, 1.483) 0.2361	
RoW	68	15 (22.1%)	53 (77.9%)	N.A. (12.62, N.A.)	61	9 (14.8%)	52 (85.2%)	N.A. (7.66, N.A.)	1.122 (0.467, 2.696) 0.7966	
ECOG Performance:										0.9240
0	114	31 (27.2%)	83 (72.8%)	22.05 (13.60, N.A.)	128	31 (24.2%)	97 (75.8%)	12.22 (7.85, N.A.)	0.578 (0.336, 0.995) 0.0479	
>= 1	189	43 (22.8%)	146 (77.2%)	25.82 (17.05, N.A.)	174	34 (19.5%)	140 (80.5%)	8.08 (8.02, N.A.)	0.724 (0.440, 1.189) 0.2016	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.20 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Three-item Index (MID=45) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.1776*
Epithelioid	236	58 (24.6%)	178 (75.4%)	25.82 (14.29, N.A.)	235	47 (20.0%)	188 (80.0%)	12.22 (8.02, N.A.)	0.697 (0.457, 1.062) 0.0925	
Non-Epithelioid	67	16 (23.9%)	51 (76.1%)	N.A. (11.07, N.A.)	67	18 (26.9%)	49 (73.1%)	8.02 (7.43, 8.15)	0.504 (0.243, 1.045) 0.0655	
Disease Stage at Study Entry:										0.3664
Stage I	12	4 (33.3%)	8 (66.7%)	N.A. (1.64, N.A.)	20	4 (20.0%)	16 (80.0%)	N.A. (7.85, N.A.)	2.141 (0.485, 9.447) 0.3149	
Stage II	23	1 (4.3%)	22 (95.7%)	N.A. (N.A., N.A.)	22	1 (4.5%)	21 (95.5%)	N.A. (N.A., N.A.)	1.099 (0.069, 17.570) 0.9470	
Stage III	103	22 (21.4%)	81 (78.6%)	N.A. (17.87, N.A.)	106	21 (19.8%)	85 (80.2%)	N.A. (8.15, N.A.)	0.543 (0.274, 1.079) 0.0814	
Stage IV	160	44 (27.5%)	116 (72.5%)	13.60 (11.01, 25.82)	149	38 (25.5%)	111 (74.5%)	8.02 (7.52, N.A.)	0.563 (0.346, 0.916) 0.0207	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.20 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Three-item Index (MID=45) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.8072
Never	127	31 (24.4%)	96 (75.6%)	23.03 (17.05, N.A.)	122	31 (25.4%)	91 (74.6%)	8.08 (8.02, N.A.)	0.602 (0.350, 1.038) 0.0680	
Former	155	38 (24.5%)	117 (75.5%)	25.82 (11.99, N.A.)	163	32 (19.6%)	131 (80.4%)	N.A. (7.85, N.A.)	0.739 (0.444, 1.229) 0.2440	
Current	18	5 (27.8%)	13 (72.2%)	13.60 (6.60, N.A.)	8	1 (12.5%)	7 (87.5%)	N.A. (0.72, N.A.)	0.841 (0.084, 8.375) 0.8824	
Prior Radiotherapy:										0.1331*
Yes	29	7 (24.1%)	22 (75.9%)	12.71 (9.63, N.A.)	28	2 (7.1%)	26 (92.9%)	N.A. (7.39, N.A.)	1.330 (0.221, 8.010) 0.7559	
No	274	67 (24.5%)	207 (75.5%)	25.82 (17.12, N.A.)	274	63 (23.0%)	211 (77.0%)	12.22 (8.02, N.A.)	0.618 (0.425, 0.900) 0.0120	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.20 (CONT.): Subgroup Time to Definitive Deterioration LCSS: Three-item Index (MID=45) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.0401**
Positive	232	50 (21.6%)	182 (78.4%)	25.82 (17.05, N.A.)	219	46 (21.0%)	173 (79.0%)	N.A. (8.02, N.A.)	0.527 (0.337, 0.824) 0.0050	
Negative	57	20 (35.1%)	37 (64.9%)	17.87 (5.52, N.A.)	78	16 (20.5%)	62 (79.5%)	12.22 (8.02, N.A.)	1.338 (0.672, 2.665) 0.4070	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Anhang 4-G 4.1.2.11: Subgruppenanalysen für den Endpunkt Gesundheitszustand gemäß EQ-5D-VAS (MID 7 mm) – Zeit bis zur dauerhaften Verschlechterung

Table 6.1.2.21: Subgroup Time to Definitive Deterioration EQ-5D-3L: VAS (MID=7) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
All Patients	303	115 (38.0%)	188 (62.0%)	18.89 (16.33, 25.82)	302	134 (44.4%)	168 (55.6%)	12.68 (9.95, 15.01)	0.665 (0.516, 0.857) 0.0016	
Age Category:										0.1911*
< 65	71	31 (43.7%)	40 (56.3%)	12.81 (6.01, 26.09)	96	37 (38.5%)	59 (61.5%)	12.85 (9.69, 19.32)	0.993 (0.614, 1.606) 0.9775	
>= 65 and <75	154	58 (37.7%)	96 (62.3%)	21.52 (16.33, 26.15)	127	60 (47.2%)	67 (52.8%)	12.68 (7.62, 15.44)	0.610 (0.424, 0.879) 0.0079	
>= 75	78	26 (33.3%)	52 (66.7%)	26.15 (12.88, N.A.)	79	37 (46.8%)	42 (53.2%)	10.25 (5.91, 18.33)	0.551 (0.332, 0.915) 0.0212	
Gender:										0.2431
Male	234	88 (37.6%)	146 (62.4%)	19.91 (15.44, 26.15)	233	112 (48.1%)	121 (51.9%)	10.84 (8.31, 13.73)	0.629 (0.475, 0.833) 0.0012	
Female	69	27 (39.1%)	42 (60.9%)	18.89 (13.63, 27.60)	69	22 (31.9%)	47 (68.1%)	16.62 (10.32, N.A.)	0.910 (0.517, 1.600) 0.7423	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.21 (CONT.): Subgroup Time to Definitive Deterioration EQ-5D-3L: VAS (MID=7) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Race:										0.6544
White	266	103 (38.7%)	163 (61.3%)	18.46 (15.47, 25.82)	250	104 (41.6%)	146 (58.4%)	12.68 (9.92, 15.70)	0.695 (0.527, 0.914) 0.0094	
Asian	26	10 (38.5%)	16 (61.5%)	20.14 (7.00, N.A.)	39	24 (61.5%)	15 (38.5%)	11.30 (6.77, 21.75)	0.621 (0.295, 1.305) 0.2087	
Other	11	2 (18.2%)	9 (81.8%)	N.A. (15.28, N.A.)	13	6 (46.2%)	7 (53.8%)	12.81 (0.92, N.A.)	1.044 (0.147, 7.410) 0.9657	
Region:										0.0889*
North America	32	7 (21.9%)	25 (78.1%)	26.15 (9.72, N.A.)	27	12 (44.4%)	15 (55.6%)	6.05 (1.45, 12.78)	0.187 (0.063, 0.558) 0.0027	
EU	177	73 (41.2%)	104 (58.8%)	18.33 (15.44, 25.43)	175	68 (38.9%)	107 (61.1%)	13.57 (9.95, 17.31)	0.796 (0.570, 1.113) 0.1830	
Asia	26	10 (38.5%)	16 (61.5%)	20.14 (7.00, N.A.)	39	24 (61.5%)	15 (38.5%)	11.30 (6.77, 21.75)	0.621 (0.295, 1.305) 0.2087	
RoW	68	25 (36.8%)	43 (63.2%)	21.52 (10.38, N.A.)	61	30 (49.2%)	31 (50.8%)	12.81 (4.50, 21.32)	0.694 (0.408, 1.183) 0.1799	
ECOG Performance:										0.2462
0	114	53 (46.5%)	61 (53.5%)	17.61 (12.88, 24.87)	128	59 (46.1%)	69 (53.9%)	13.60 (10.02, 16.62)	0.773 (0.531, 1.125) 0.1785	
>= 1	189	62 (32.8%)	127 (67.2%)	25.30 (15.64, 30.42)	174	75 (43.1%)	99 (56.9%)	10.32 (8.02, 15.44)	0.607 (0.432, 0.853) 0.0041	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.21 (CONT.): Subgroup Time to Definitive Deterioration EQ-5D-3L: VAS (MID=7) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Histology (IVRS):										0.0046**
Epithelioid	236	91 (38.6%)	145 (61.4%)	18.33 (15.47, 25.82)	235	96 (40.9%)	139 (59.1%)	13.73 (10.32, 18.33)	0.802 (0.601, 1.070) 0.1344	
Non-Epithelioid	67	24 (35.8%)	43 (64.2%)	21.52 (9.69, N.A.)	67	38 (56.7%)	29 (43.3%)	8.02 (2.33, 10.97)	0.371 (0.220, 0.623) 0.0002	
Disease Stage at Study Entry:										0.0658*
Stage I	12	7 (58.3%)	5 (41.7%)	6.13 (0.46, N.A.)	20	10 (50.0%)	10 (50.0%)	12.85 (7.85, N.A.)	1.498 (0.559, 4.015) 0.4219	
Stage II	23	8 (34.8%)	15 (65.2%)	18.46 (8.71, N.A.)	22	6 (27.3%)	16 (72.7%)	32.99 (10.84, N.A.)	1.369 (0.467, 4.009) 0.5669	
Stage III	103	34 (33.0%)	69 (67.0%)	26.09 (18.33, N.A.)	106	46 (43.4%)	60 (56.6%)	12.81 (10.02, 19.58)	0.486 (0.308, 0.764) 0.0018	
Stage IV	160	64 (40.0%)	96 (60.0%)	15.47 (12.45, 26.15)	149	70 (47.0%)	79 (53.0%)	8.02 (6.21, 13.60)	0.655 (0.465, 0.923) 0.0156	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.21 (CONT.): Subgroup Time to Definitive Deterioration EQ-5D-3L: VAS (MID=7) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
Smoking Status:										0.9980
Never	127	50 (39.4%)	77 (60.6%)	20.14 (14.00, 26.09)	122	57 (46.7%)	65 (53.3%)	10.74 (8.54, 15.44)	0.650 (0.441, 0.958) 0.0293	
Former	155	57 (36.8%)	98 (63.2%)	18.46 (14.09, 28.52)	163	72 (44.2%)	91 (55.8%)	12.81 (8.31, 17.31)	0.683 (0.482, 0.968) 0.0320	
Current	18	8 (44.4%)	10 (55.6%)	30.42 (5.75, 30.42)	8	3 (37.5%)	5 (62.5%)	19.58 (0.92, N.A.)	0.587 (0.144, 2.390) 0.4574	
Prior Radiotherapy:										0.9048
Yes	29	8 (27.6%)	21 (72.4%)	30.42 (9.69, N.A.)	28	9 (32.1%)	19 (67.9%)	16.62 (4.50, N.A.)	0.650 (0.233, 1.815) 0.4111	
No	274	107 (39.1%)	167 (60.9%)	18.46 (15.44, 25.43)	274	125 (45.6%)	149 (54.4%)	11.30 (9.92, 13.80)	0.667 (0.514, 0.864) 0.0022	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
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Table 6.1.2.21 (CONT.): Subgroup Time to Definitive Deterioration EQ-5D-3L: VAS (MID=7) (Randomized Population) (N=605)

	Nivolumab plus Ipilimumab [A]				Pemetrexed plus Cisplatin or Carboplatin [B]				[A] versus [B]	
Domains	N	Patients with event n(%)	Censored patients n(%)	KME [1] [95% CI] (in months)	N	Patients with event n(%)	Censored patients n(%)	KME[1] [95% CI] (in months)	HR[2] [95% CI] p-value	Group by Treat Arm Int. p-value [3][4]
PD-L1 Status:										0.4616
Positive	232	87 (37.5%)	145 (62.5%)	18.46 (15.28, 25.82)	219	89 (40.6%)	130 (59.4%)	12.81 (9.92, 16.62)	0.699 (0.520, 0.941) 0.0183	
Negative	57	21 (36.8%)	36 (63.2%)	26.09 (9.69, N.A.)	78	43 (55.1%)	35 (44.9%)	10.32 (7.85, 15.01)	0.549 (0.322, 0.938) 0.0282	

[1] KME of median time. Two-sided 95% CI is computed by Brookmeyer and Crowley method (log log transformation).
[2] Cox proportional hazard model with overall/all patients models including IVRS histology and IVRS sex as stratification variables and baseline PRO score as a covariate. Subgroup models excluded stratification variables. Hazard ratio is Nivolumab plus Ipilimumab over Pemetrexed plus Cisplatin or Carboplatin, with hazard ratios greater than 1 indicating a larger number of events occurring in the Nivolumab plus Ipilimumab arm over a unit of time.
[3] Cox proportional hazard model with treatment, subgroup and treatment by subgroup interaction, treating baseline PRO score as a covariate.
[4] A p-value of <0.20 but >=0.05 is indicated by 1 asterisk, a p-value <0.05 is indicated by 2 asterisks.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -06.00- AMNOG TTE_v0_5.sas EXECUTED: May 14, 2021 at 17:35:16 by alejandro.moreno-koe

Anhang 4-G 4.1.3: Subgruppenanalysen für Endpunkte Verträglichkeit aus CA209-743

Subgruppenanalysen für die Endpunkte unerwünschte Ereignisse ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE: jegliches UE, UE Grad ≥ 3, schwerwiegende UE und Therapieabbruch wegen UE

Anhang 4-G 4.1.3.1: Subgruppenanalysen für den Endpunkt jegliches UE ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE

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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	298 (99.3)	0.26 (0.20, 0.39)	284	276 (97.2)	0.13 (0.10, 0.20)	0.866 (0.734, 1.021) 0.0857	
AGE CATEGORIZATION								0.5477
< 65	71	71 (100.0)	0.39 (0.16, 0.49)	87	85 (97.7)	0.13 (0.10, 0.26)	0.909 (0.662, 1.248) 0.6038	
>= 65 AND < 75	151	149 (98.7)	0.30 (0.20, 0.49)	123	119 (96.7)	0.13 (0.10, 0.23)	0.787 (0.617, 1.004) 0.0542	
>= 75	78	78 (100.0)	0.13 (0.07, 0.30)	74	72 (97.3)	0.15 (0.10, 0.30)	0.969 (0.702, 1.337) 0.7870	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubhr-ebr2252.sas 04FEB2021:12:49:12

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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3798
MALE	232	231 (99.6)	0.25 (0.16, 0.33)	221	215 (97.3)	0.13 (0.10, 0.20)	0.901 (0.748, 1.085) 0.2774	
FEMALE	68	67 (98.5)	0.46 (0.23, 0.49)	63	61 (96.8)	0.13 (0.07, 0.39)	0.792 (0.556, 1.128) 0.1929	
RACE								0.2859
WHITE	263	261 (99.2)	0.30 (0.23, 0.43)	233	225 (96.6)	0.20 (0.10, 0.26)	0.890 (0.744, 1.065) 0.2115	
ASIAN	26	26 (100.0)	0.20 (0.07, 0.33)	38	38 (100.0)	0.10 (0.07, 0.10)	0.562 (0.332, 0.951) 0.0375	
OTHER	11	11 (100.0)	0.13 (0.03, 0.69)	13	13 (100.0)	0.20 (0.13, 0.59)	1.523 (0.657, 3.533) 0.3136	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.1105
NORTH AMERICA	32	32 (100.0)	0.10 (0.03, 0.20)	25	25 (100.0)	0.10 (0.03, 0.23)	1.151 (0.663, 1.999) 0.5814	
EUROPE	175	173 (98.9)	0.49 (0.30, 0.49)	164	160 (97.6)	0.20 (0.13, 0.33)	0.781 (0.629, 0.971) 0.0220	
ASIA	26	26 (100.0)	0.20 (0.07, 0.33)	38	38 (100.0)	0.10 (0.07, 0.10)	0.562 (0.332, 0.951) 0.0375	
REST OF WORLD	67	67 (100.0)	0.23 (0.10, 0.30)	57	53 (93.0)	0.16 (0.10, 0.59)	1.150 (0.800, 1.652) 0.4248	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.7001
0	113	112 (99.1)	0.26 (0.16, 0.49)	121	114 (94.2)	0.20 (0.10, 0.33)	0.892 (0.686, 1.160) 0.4158	
>= 1	187	186 (99.5)	0.30 (0.16, 0.43)	163	162 (99.4)	0.13 (0.10, 0.16)	0.831 (0.671, 1.028) 0.0782	
IVRS HISTOLOGY								0.9302
EPITHELIOID	233	232 (99.6)	0.30 (0.23, 0.46)	219	211 (96.3)	0.16 (0.10, 0.26)	0.868 (0.719, 1.047) 0.1422	
NON-EPITHELIOID	67	66 (98.5)	0.23 (0.10, 0.43)	65	65 (100.0)	0.10 (0.10, 0.16)	0.835 (0.589, 1.183) 0.3003	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.5310
STAGE I	12	12 (100.0)	0.49 (0.07, 0.72)	17	17 (100.0)	0.26 (0.03, 0.72)	0.823 (0.383, 1.770) 0.6255	
STAGE II	23	23 (100.0)	0.16 (0.03, 0.49)	21	20 (95.2)	0.10 (0.07, 0.72)	1.006 (0.550, 1.840) 0.9802	
STAGE III	102	101 (99.0)	0.20 (0.13, 0.39)	101	100 (99.0)	0.13 (0.10, 0.16)	0.741 (0.559, 0.984) 0.0360	
STAGE IV	158	157 (99.4)	0.31 (0.23, 0.46)	140	135 (96.4)	0.15 (0.10, 0.30)	0.938 (0.744, 1.181) 0.5775	
NOT REPORTED	5	5 (100.0)	0.10 (0.03, 1.31)	5	4 (80.0)	0.20 (0.03, 1.38)	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9970
NEVER	124	122 (98.4)	0.38 (0.23, 0.49)	116	112 (96.6)	0.16 (0.10, 0.30)	0.888 (0.686, 1.149) 0.3504	
FORMER	155	155 (100.0)	0.23 (0.13, 0.33)	153	149 (97.4)	0.13 (0.10, 0.20)	0.879 (0.701, 1.102) 0.2628	
CURRENT	18	18 (100.0)	0.53 (0.16, 0.95)	8	8 (100.0)	0.31 (0.03, 1.41)	0.764 (0.326, 1.791) 0.5387	
UNKNOWN	3	3 (100.0)	0.16 (0.07, 0.95)	7	7 (100.0)	0.26 (0.03, 0.85)	1.009 (0.247, 4.132) 0.9803	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubhr-ebr2252.sas 04FEB2021:12:49:12

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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.5448
YES	28	28 (100.0)	0.46 (0.13, 0.49)	26	25 (96.2)	0.13 (0.07, 0.69)	1.004 (0.583, 1.729) 0.9502	
NO	272	270 (99.3)	0.26 (0.20, 0.36)	258	251 (97.3)	0.13 (0.10, 0.20)	0.851 (0.716, 1.011) 0.0689	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	297 (99.3)	N.M.E.	284	276 (97.2)	N.M.E.	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubhr-ebr2252.sas 04FEB2021:12:49:12

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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3732
POSITIVE	229	227 (99.1)	0.26 (0.20, 0.39)	203	196 (96.6)	0.13 (0.10, 0.23)	0.921 (0.760, 1.116) 0.4093	
NEGATIVE	57	57 (100.0)	0.36 (0.13, 0.49)	76	75 (98.7)	0.13 (0.10, 0.20)	0.779 (0.547, 1.108) 0.1504	
NOT REPORTED	14	14 (100.0)	0.25 (0.07, 1.41)	5	5 (100.0)	0.03 (0.03, 0.72)	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubhr-ebr2252.sas 04FEB2021:12:49:12

Anhang 4-G 4.1.3.2: Subgruppenanalysen für den Endpunkt UE Grad ≥ 3 ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE

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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
OVERALL	300	178 (59.3)	7.13 (5.26, 9.79)	284	139 (48.9)	6.77 (3.55, N.A.)	0.911 (0.721, 1.151) 0.4338	
AGE CATEGORIZATION								0.7730
< 65	71	38 (53.5)	8.44 (4.21, 19.98)	87	36 (41.4)	N.A. (3.52, N.A.)	0.969 (0.597, 1.572) 0.8992	
>= 65 AND < 75	151	85 (56.3)	9.10 (6.11, 12.52)	123	57 (46.3)	N.A. (3.38, N.A.)	0.840 (0.588, 1.200) 0.3382	
>= 75	78	55 (70.5)	3.61 (1.81, 5.95)	74	46 (62.2)	3.06 (2.10, 6.34)	0.967 (0.644, 1.452) 0.8691	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubhr-ebr2252.sas 04FEB2021:12:49:34

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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								0.4592
MALE	232	141 (60.8)	6.11 (4.04, 9.03)	221	109 (49.3)	6.70 (3.45, N.A.)	0.976 (0.752, 1.267) 0.8551	
FEMALE	68	37 (54.4)	10.87 (6.93, 14.52)	63	30 (47.6)	N.A. (2.56, N.A.)	0.702 (0.412, 1.195) 0.1912	
RACE								0.1903
WHITE	263	154 (58.6)	7.75 (4.99, 10.12)	233	106 (45.5)	N.A. (4.17, N.A.)	0.988 (0.762, 1.281) 0.9264	
ASIAN	26	19 (73.1)	5.55 (2.73, 9.26)	38	24 (63.2)	3.42 (1.25, N.A.)	0.873 (0.457, 1.666) 0.6740	
OTHER	11	5 (45.5)	15.93 (1.18, N.A.)	13	9 (69.2)	1.61 (0.46, N.A.)	0.402 (0.123, 1.310) 0.1180	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								0.9621
NORTH AMERICA	32	19 (59.4)	6.93 (2.79, 11.07)	25	12 (48.0)	5.75 (1.87, N.A.)	0.876 (0.405, 1.895) 0.7331	
EUROPE	175	101 (57.7)	6.93 (4.60, 12.35)	164	77 (47.0)	N.A. (3.29, N.A.)	0.966 (0.709, 1.316) 0.8273	
ASIA	26	19 (73.1)	5.55 (2.73, 9.26)	38	24 (63.2)	3.42 (1.25, N.A.)	0.873 (0.457, 1.666) 0.6740	
REST OF WORLD	67	39 (58.2)	8.11 (3.94, 12.68)	57	26 (45.6)	N.A. (2.43, N.A.)	0.879 (0.515, 1.500) 0.6371	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 PERFORMANCE STATUS								0.8199
0	113	67 (59.3)	8.11 (4.99, 12.68)	121	57 (47.1)	N.A. (2.79, N.A.)	0.872 (0.600, 1.268) 0.4742	
>= 1	187	111 (59.4)	6.93 (4.04, 9.79)	163	82 (50.3)	6.41 (3.45, N.A.)	0.934 (0.692, 1.261) 0.6570	
IVRS HISTOLOGY								0.1977
EPITHELIOID	233	137 (58.8)	8.21 (5.95, 10.61)	219	99 (45.2)	N.A. (5.55, N.A.)	0.960 (0.729, 1.263) 0.7713	
NON-EPITHELIOID	67	41 (61.2)	4.63 (3.19, 9.03)	65	40 (61.5)	2.76 (1.87, 5.78)	0.773 (0.493, 1.210) 0.2600	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 STUDY ENTRY								0.3817
STAGE I	12	7 (58.3)	6.75 (0.33, 12.52)	17	8 (47.1)	N.A. (2.89, N.A.)	1.352 (0.467, 3.912) 0.5766	
STAGE II	23	15 (65.2)	4.60 (2.20, 21.68)	21	8 (38.1)	N.A. (3.91, N.A.)	1.925 (0.806, 4.596) 0.1343	
STAGE III	102	62 (60.8)	9.20 (6.47, 12.68)	101	49 (48.5)	N.A. (2.76, N.A.)	0.708 (0.466, 1.075) 0.1031	
STAGE IV	158	90 (57.0)	6.60 (4.04, 10.18)	140	73 (52.1)	4.90 (2.76, N.A.)	0.866 (0.629, 1.192) 0.3783	
NOT REPORTED	5	4 (80.0)	3.88 (0.26, N.A.)	5	1 (20.0)	N.A. (0.66, N.A.)	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
TOBACCO USE								0.7819
NEVER	124	65 (52.4)	10.87 (6.93, 13.37)	116	52 (44.8)	N.A. (3.58, N.A.)	0.789 (0.532, 1.168) 0.2343	
FORMER	155	96 (61.9)	5.26 (3.71, 9.43)	153	78 (51.0)	5.78 (2.86, N.A.)	0.991 (0.725, 1.354) 0.9587	
CURRENT	18	14 (77.8)	4.44 (1.84, 8.44)	8	5 (62.5)	4.11 (0.13, 6.77)	0.741 (0.256, 2.146) 0.5800	
UNKNOWN	3	3 (100.0)	1.87 (0.23, 3.88)	7	4 (57.1)	0.85 (0.07, N.A.)	1.605 (0.357, 7.227) 0.5337	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 RADIOTHERAPY								0.5760
YES	28	15 (53.6)	7.46 (1.84, N.A.)	26	13 (50.0)	3.06 (1.08, N.A.)	0.856 (0.397, 1.847) 0.6941	
NO	272	163 (59.9)	6.93 (5.26, 9.79)	258	126 (48.8)	6.77 (3.58, N.A.)	0.917 (0.717, 1.172) 0.4909	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	178 (59.5)	N.M.E.	284	139 (48.9)	N.M.E.	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Anhang 4-G 4.1.3.3: Subgruppenanalysen für die Endpunkt schwerwiegende UE ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE

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Subgroup Time-Adjusted Analyses of Adverse Events for
Adverse Events with CTCAE Grade 3-4-5
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Adverse Events with CTCAE Grade 3-4-5	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
PD-L1								0.0814
POSITIVE	229	132 (57.6)	7.46 (4.99, 10.61)	203	104 (51.2)	5.75 (2.89, N.A.)	0.835 (0.637, 1.094) 0.1900	
NEGATIVE	57	37 (64.9)	7.13 (3.25, 10.12)	76	32 (42.1)	N.A. (3.55, N.A.)	1.147 (0.688, 1.913) 0.5989	
NOT REPORTED	14	9 (64.3)	3.98 (1.41, N.A.)	5	3 (60.0)	6.70 (0.99, N.A.)	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
OVERALL	300	163 (54.3)	9.33 (7.56, 12.52)	284	77 (27.1)	N.A. (N.A., N.A.)	1.715 (1.291, 2.279) 0.0002	
AGE CATEGORIZATION								0.3264
< 65	71	34 (47.9)	12.45 (4.44, N.A.)	87	27 (31.0)	N.A. (N.A., N.A.)	1.333 (0.785, 2.262) 0.2849	
>= 65 AND < 75	151	76 (50.3)	12.35 (8.67, 16.16)	123	25 (20.3)	N.A. (N.A., N.A.)	1.961 (1.219, 3.156) 0.0047	
>= 75	78	53 (67.9)	4.83 (2.83, 7.56)	74	25 (33.8)	N.A. (6.34, N.A.)	1.970 (1.204, 3.224) 0.0060	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0022**
MALE	232	137 (59.1)	7.89 (4.60, 9.66)	221	56 (25.3)	N.A. (N.A., N.A.)	2.185 (1.582, 3.017) <0.0001	
FEMALE	68	26 (38.2)	17.87 (14.42, N.A.)	63	21 (33.3)	N.A. (N.A., N.A.)	0.680 (0.355, 1.302) 0.2416	
RACE								0.0802
WHITE	263	143 (54.4)	9.30 (7.46, 12.52)	233	61 (26.2)	N.A. (N.A., N.A.)	1.757 (1.284, 2.403) 0.0004	
ASIAN	26	17 (65.4)	3.35 (0.92, 16.43)	38	11 (28.9)	N.A. (6.34, N.A.)	2.758 (1.247, 6.100) 0.0093	
OTHER	11	3 (27.3)	19.15 (4.37, N.A.)	13	5 (38.5)	N.A. (0.95, N.A.)	0.221 (0.026, 1.897) 0.1323	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.3411
NORTH AMERICA	32	17 (53.1)	10.18 (3.88, 22.24)	25	9 (36.0)	N.A. (4.30, N.A.)	1.147 (0.483, 2.727) 0.7574	
EUROPE	175	94 (53.7)	9.66 (6.37, 16.16)	164	46 (28.0)	N.A. (N.A., N.A.)	1.563 (1.080, 2.261) 0.0170	
ASIA	26	17 (65.4)	3.35 (0.92, 16.43)	38	11 (28.9)	N.A. (6.34, N.A.)	2.758 (1.247, 6.100) 0.0093	
REST OF WORLD	67	35 (52.2)	8.87 (4.44, N.A.)	57	11 (19.3)	N.A. (N.A., N.A.)	2.359 (1.165, 4.778) 0.0140	

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(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 PERFORMANCE STATUS								0.0862
0	113	65 (57.5)	8.61 (5.62, 13.08)	121	26 (21.5)	N.A. (N.A., N.A.)	2.241 (1.392, 3.606) 0.0006	
>= 1	187	98 (52.4)	9.33 (6.51, 15.38)	163	51 (31.3)	N.A. (N.A., N.A.)	1.447 (1.014, 2.065) 0.0409	
IVRS HISTOLOGY								0.0311**
EPITHELIOID	233	131 (56.2)	9.23 (6.37, 12.45)	219	53 (24.2)	N.A. (N.A., N.A.)	1.979 (1.417, 2.764) <0.0001	
NON-EPITHELIOID	67	32 (47.8)	9.72 (4.37, N.A.)	65	24 (36.9)	N.A. (4.47, N.A.)	1.132 (0.650, 1.973) 0.6645	

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Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7208
STAGE I	12	8 (66.7)	2.45 (0.49, 12.52)	17	7 (41.2)	N.A. (3.06, N.A.)	2.091 (0.727, 6.018) 0.1630	
STAGE II	23	14 (60.9)	5.36 (1.74, N.A.)	21	5 (23.8)	N.A. (5.75, N.A.)	3.130 (1.114, 8.794) 0.0226	
STAGE III	102	60 (58.8)	10.18 (6.37, 17.87)	101	30 (29.7)	N.A. (N.A., N.A.)	1.433 (0.893, 2.299) 0.1341	
STAGE IV	158	78 (49.4)	9.30 (7.89, 14.52)	140	35 (25.0)	N.A. (N.A., N.A.)	1.692 (1.116, 2.564) 0.0122	
NOT REPORTED	5	3 (60.0)	3.88 (0.26, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
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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 is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.4335
NEVER	124	58 (46.8)	13.08 (8.61, 17.87)	116	32 (27.6)	N.A. (N.A., N.A.)	1.208 (0.758, 1.926) 0.4285	
FORMER	155	94 (60.6)	5.78 (3.94, 9.66)	153	42 (27.5)	N.A. (N.A., N.A.)	2.175 (1.492, 3.172) <0.0001	
CURRENT	18	9 (50.0)	10.61 (4.34, N.A.)	8	1 (12.5)	N.A. (1.45, N.A.)	3.268 (0.402, 26.583) 0.2409	
UNKNOWN	3	2 (66.7)	3.88 (0.23, N.A.)	7	2 (28.6)	N.A. (0.33, N.A.)	2.179 (0.302, 15.720) 0.4289	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.5035
YES	28	16 (57.1)	4.37 (0.82, N.A.)	26	6 (23.1)	N.A. (N.A., N.A.)	2.597 (0.999, 6.754) 0.0431	
NO	272	147 (54.0)	9.33 (7.89, 12.52)	258	71 (27.5)	N.A. (N.A., N.A.)	1.642 (1.218, 2.213) 0.0010	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	163 (54.5)	N.M.E.	284	77 (27.1)	N.M.E.	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
Serious Adverse Events
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

Serious Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3780
POSITIVE	229	124 (54.1)	9.33 (7.46, 12.45)	203	59 (29.1)	N.A. (N.A., N.A.)	1.564 (1.129, 2.165) 0.0067	
NEGATIVE	57	29 (50.9)	12.52 (4.50, 21.68)	76	16 (21.1)	N.A. (N.A., N.A.)	2.224 (1.174, 4.213) 0.0118	
NOT REPORTED	14	10 (71.4)	4.83 (1.18, 16.16)	5	2 (40.0)	6.77 (1.02, N.A.)	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Anhang 4-G 4.1.3.4: Subgruppenanalysen für die Endpunkt Therapieabbruch wegen UE ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE

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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
OVERALL	300	92 (30.7)	22.11 (17.58, N.A.)	284	58 (20.4)	N.A. (N.A., N.A.)	0.991 (0.691, 1.420) 0.9580	
AGE CATEGORIZATION								0.4939
< 65	71	15 (21.1)	19.65 (16.66, N.A.)	87	17 (19.5)	N.A. (N.A., N.A.)	0.580 (0.255, 1.318) 0.1877	
>= 65 AND < 75	151	48 (31.8)	22.11 (16.20, N.A.)	123	21 (17.1)	N.A. (N.A., N.A.)	1.126 (0.639, 1.983) 0.6824	
>= 75	78	29 (37.2)	21.68 (9.07, N.A.)	74	20 (27.0)	N.A. (N.A., N.A.)	1.131 (0.625, 2.047) 0.6830	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								0.7732
MALE	232	74 (31.9)	19.98 (16.66, N.A.)	221	49 (22.2)	N.A. (N.A., N.A.)	0.944 (0.635, 1.404) 0.7766	
FEMALE	68	18 (26.5)	N.A. (17.87, N.A.)	63	9 (14.3)	N.A. (N.A., N.A.)	1.243 (0.524, 2.949) 0.6217	
RACE								0.2513
WHITE	263	81 (30.8)	23.10 (17.87, N.A.)	233	43 (18.5)	N.A. (N.A., N.A.)	1.138 (0.763, 1.697) 0.5280	
ASIAN	26	10 (38.5)	17.31 (6.60, N.A.)	38	12 (31.6)	N.A. (4.07, N.A.)	0.747 (0.280, 1.992) 0.5604	
OTHER	11	1 (9.1)	N.A. (16.66, N.A.)	13	3 (23.1)	N.A. (1.77, N.A.)	<0.001 (<0.001, N.A.) 0.0928	

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Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								0.1116
NORTH AMERICA	32	8 (25.0)	N.A. (17.02, N.A.)	25	2 (8.0)	N.A. (N.A., N.A.)	2.702 (0.561, 13.012) 0.1966	
EUROPE	175	54 (30.9)	23.10 (17.87, N.A.)	164	39 (23.8)	N.A. (N.A., N.A.)	0.821 (0.520, 1.294) 0.3941	
ASIA	26	10 (38.5)	17.31 (6.60, N.A.)	38	12 (31.6)	N.A. (4.07, N.A.)	0.747 (0.280, 1.992) 0.5604	
REST OF WORLD	67	20 (29.9)	N.A. (12.42, N.A.)	57	5 (8.8)	N.A. (N.A., N.A.)	2.311 (0.817, 6.540) 0.1043	

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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 is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 PERFORMANCE STATUS								0.0570
0	113	40 (35.4)	17.87 (16.20, N.A.)	121	20 (16.5)	N.A. (N.A., N.A.)	1.414 (0.790, 2.531) 0.2417	
>= 1	187	52 (27.8)	N.A. (17.87, N.A.)	163	38 (23.3)	N.A. (N.A., N.A.)	0.786 (0.496, 1.246) 0.3038	
IVRS HISTOLOGY								0.4040
EPITHELIOID	233	67 (28.8)	23.10 (17.58, N.A.)	219	38 (17.4)	N.A. (N.A., N.A.)	1.082 (0.700, 1.672) 0.7244	
NON-EPITHELIOID	67	25 (37.3)	22.11 (8.77, N.A.)	65	20 (30.8)	N.A. (N.A., N.A.)	0.815 (0.427, 1.557) 0.5331	

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(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 STUDY ENTRY								0.3085
STAGE I	12	6 (50.0)	N.A. (0.56, N.A.)	17	4 (23.5)	N.A. (3.75, N.A.)	3.154 (0.883, 11.262) 0.0623	
STAGE II	23	8 (34.8)	21.68 (8.64, N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	1.608 (0.384, 6.736) 0.5119	
STAGE III	102	34 (33.3)	22.11 (17.58, N.A.)	101	24 (23.8)	N.A. (N.A., N.A.)	0.721 (0.392, 1.326) 0.2902	
STAGE IV	158	42 (26.6)	N.A. (16.20, N.A.)	140	27 (19.3)	N.A. (N.A., N.A.)	0.961 (0.570, 1.619) 0.8793	
NOT REPORTED	5	2 (40.0)	N.A. (0.49, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

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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 is to assess the significance of the interaction between treatment and the subgroup
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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
TOBACCO USE								0.5938
NEVER	124	29 (23.4)	N.A. (16.66, N.A.)	116	23 (19.8)	N.A. (N.A., N.A.)	0.643 (0.341, 1.214) 0.1695	
FORMER	155	53 (34.2)	19.98 (17.31, 23.10)	153	31 (20.3)	N.A. (N.A., N.A.)	1.268 (0.789, 2.038) 0.3262	
CURRENT	18	9 (50.0)	8.77 (5.19, N.A.)	8	3 (37.5)	N.A. (1.25, N.A.)	0.695 (0.172, 2.801) 0.6066	
UNKNOWN	3	1 (33.3)	N.A. (1.28, N.A.)	7	1 (14.3)	N.A. (1.41, N.A.)	2.449 (0.151, 39.712) 0.5151	

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(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 RADIOTHERAPY								0.6600
YES	28	7 (25.0)	N.A. (8.64, N.A.)	26	5 (19.2)	N.A. (N.A., N.A.)	0.523 (0.125, 2.188) 0.3662	
NO	272	85 (31.3)	21.68 (17.31, N.A.)	258	53 (20.5)	N.A. (N.A., N.A.)	1.041 (0.717, 1.511) 0.8342	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	92 (30.8)	N.M.E.	284	58 (20.4)	N.M.E.	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
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(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events for
AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone
on Hazard Ratio, Excluding Progression Terms
All Treated Subjects

AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
PD-L1								0.9676
POSITIVE	229	72 (31.4)	19.65 (16.66, N.A.)	203	42 (20.7)	N.A. (N.A., N.A.)	0.979 (0.645, 1.484) 0.9183	
NEGATIVE	57	16 (28.1)	21.68 (17.87, N.A.)	76	15 (19.7)	N.A. (N.A., N.A.)	1.081 (0.503, 2.323) 0.8420	
NOT REPORTED	14	4 (28.6)	N.A. (7.69, N.A.)	5	1 (20.0)	N.A. (2.96, N.A.)	N.M.E.	

April 2020 DBL, HR = hazard ratio; KME=Kaplan-Meier estimate. (1) KME of median time
Includes events reported between first dose and 100 days after last dose of study therapy.
(2) Unstratified Cox proportional hazard model. HR is Nivo+Ipi over Chemo (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
If all subgroups individually have less than 10 events and there are less than 2 subgroups which individually have 10 or more subjects display the corresponding test for interaction p-value as n.m.e.
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Anhang 4-G 4.2: Subgruppenanalysen zu Endpunkten dieses Anhangs aus CA209-743

Matrix der durchgeführten Subgruppenanalysen

Endpunkte Studie CA209-743	**Altersgruppe**	**Geschlecht**	**Ethnie**	**Region**	**ECOG Performance Status**	**Tumorhistologie lt. IVRS**	**Krankheitsstadium**	**Raucherstatus**	**Vorherige Radiotherapie**	**Vorherige systemische Therapie**	**PD-L1-Status**
Endpunkte Verträglichkeit – UE von besonderem Interesse (AESI)											
jegliches spezifisches immunvermitteltes UE	○	○	○	○	○	○	○	○	○	n.d.(2)	○
jegliches spezifisches UE	○	○	○	○	○	○	○	○	○	n.d.(2)	○
jegliches weiteres UE von besonderem Interesse	○	○	○	○	○	○	○	○	○	n.d.(2)	○
Endpunkte Verträglichkeit – UE auf SOC/PT-Ebene(1)											
UE Pyrexie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Periphere Ödeme (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Schüttelfrost (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Unwohlsein (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Gastrointestinale Erkrankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Diarrhö (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Übelkeit (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Konstipation (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Erbrechen (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○

Endpunkte Studie CA209-743	**Altersgruppe**	**Geschlecht**	**Ethnie**	**Region**	**ECOG Performance Status**	**Tumorhistologie lt. IVRS**	**Krankheitsstadium**	**Raucherstatus**	**Vorherige Radiotherapie**	**Vorherige systemische Therapie**	**PD-L1-Status**
UE Dyspnoe (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Husten (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Pleuraerguss(PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Pneumonitis (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Produktiver Husten (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Epistaxis (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Schluckauf (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Rhinorrhö (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Erkrankungen der Haut und des Unterhautgewebes (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Pruritus (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Ausschlag (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Alopezie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Infektionen und parasitäre Erkrankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Verminderter Appetit (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Hypomagnesiämie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○

Endpunkte Studie CA209-743	**Altersgruppe**	**Geschlecht**	**Ethnie**	**Region**	**ECOG Performance Status**	**Tumorhistologie lt. IVRS**	**Krankheitsstadium**	**Raucherstatus**	**Vorherige Radiotherapie**	**Vorherige systemische Therapie**	**PD-L1-Status**
UE Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Arthralgie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Myalgie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Lipase erhöht (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Amylase erhöht (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Alanin-Aminotransferase erhöht (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Alkalische Phosphatase im Blut erhöht (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Aspartat-Aminotransferase erhöht (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Dysgeusie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Periphere Neuropathie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Erkrankungen des Blutes und des Lymphsystems (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Anämie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Neutropenie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Thrombozytopenie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Leukopenie (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○

Endpunkte Studie CA209-743	**Altersgruppe**	**Geschlecht**	**Ethnie**	**Region**	**ECOG Performance Status**	**Tumorhistologie lt. IVRS**	**Krankheitsstadium**	**Raucherstatus**	**Vorherige Radiotherapie**	**Vorherige systemische Therapie**	**PD-L1-Status**
UE Endokrine Erkrankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Hypothyreose (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Hyperthyreose (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Verletzungen, Vergiftungen und durch Eingriffe bedingte Komplikationen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Infusionsbedingte Reaktion (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Herz-Kreislauf-Erkrankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Hepatobiläre Erkrankung (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Augenerkankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Lakrimation erhöht (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Untersuchungen Grad ≥ 3 (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Lipase erhöht Grad ≥ 3 (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Asthenie Grad ≥ 3 (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Erkrankungen des Blutes und des Lymphsystems Grad ≥ 3 (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Anämie Grad ≥ 3 (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Neutropenie Grad ≥ 3 (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○

Endpunkte Studie CA209-743	**Altersgruppe**	**Geschlecht**	**Ethnie**	**Region**	**ECOG Performance Status**	**Tumorhistologie lt. IVRS**	**Krankheitsstadium**	**Raucherstatus**	**Vorherige Radiotherapie**	**Vorherige systemische Therapie**	**PD-L1-Status**
UE Thrombozytopenie Grad ≥ 3 (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Hepatobiliäre Erkrankung Grad ≥ 3 (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Erkrankungen des Nervensystems Grad ≥ 3 (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Erkrankungen der Haut und des Unterhautgewebes Grad ≥ 3 (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
UE Erkrankungen des Muskel-Skelett-Systems und des Bindegewebes Grad ≥ 3 (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
SUE Erkrankungen der Atemwege, des Brustkorbs und des Mediastinums (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
SUE Hepatobiliäre Erkrankungen (PT)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
SUE Erkrankungen des Nervensystems (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
SUE Nieren- und Harnwegserkrankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
SUE Endokrine Erkrankungen (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○
SUE Erkrankungen des Blutes und des Lymphsystems (SOC)	○	○	○	○	○	○	○	○	○	n.d.(2)	○

○ = Für das vorliegende Dossier durchgeführte Subgruppenanalyse; AESI = adverse event(s) of special interest; ECOG = Eastern Cooperative Oncology Group; IVRS = Interactive Voice Recognition System; LCSS-Meso = Lung Cancer Symptom Scale - Mesothelioma adaptation; n.d.: Subgruppenanalyse nicht durchgeführt; PD-L1 = Programmed Death Ligand-1; PT = Preferred Term; SOC = Systemorganklasse; SUE = Schwerwiegende(s) unerwünschte(s) Ereignis(se); UE = Unerwünschte(s) Ereignis(se)

Endpunkte Studie CA209-743	**Altersgruppe**	**Geschlecht**	**Ethnie**	**Region**	**ECOG Performance Status**	**Tumorhistologie lt. IVRS**	**Krankheitsstadium**	**Raucherstatus**	**Vorherige Radiotherapie**	**Vorherige systemische Therapie**	**PD-L1-Status**
(1) Subgruppenanalysen werden nur für diejenigen UE auf SOC/PT-Ebene dargestellt, für welche die Gesamtanalyse gemäß 95 %-KI statistisch signifikant war. Zudem wurden keine Subgruppenanalysen für PT der Progressionsereignisse durchgeführt, da die Hauptanalyse der UE-Hauptkategorien ohne Erfassung des Progresses der Grunderkrankung erfolgte.											
(2) Für das Subgruppenmerkmal Vorherige systemische Therapie war in der Subgruppe Ja nur 1 Patient dokumentiert (Nivolumab + Ipilimumab-Arm). Dieser Patient erhielt Bevacizumab tatsächlich als Folgetherapie, allerdings wurde ein falsches Startdatum für diese Folgetherapie dokumentiert. Somit habentatsächlich keine Patienten in der Studie CA209-743 eine vorherige systemische Therapie erhalten.											

Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie CA209-743 und alle Effektmodifikatoren

Endpunkte(1) Studie CA209-743	**Alters-gruppe I**	**Geschlecht**	**Ethnie I**	**Region**	**ECOG Perfor-mance Status**	**Tumor-histologie lt. IVRS**	**Krank-heits-stadium**	**Raucher-status**	**Vorherige Radio-therapie**	**Vorherige systemi-sche Therapie**	**PD-L1-Status**
Endpunkte Verträglichkeit(2) – UE von besonderem Interesse (AESI)											
jegliches spezifisches immunvermitteltes UE	0,5219	0,8342	0,9995	0,6277	0,9605	0,6177	0,9687	0,4816	0,9851	N.M.E.	0,8110
jegliches spezifisches UE	0,5602	0,0821	0,1068	0,2287	0,6899	**0,0440***	0,9969	0,7224	0,8302	N.M.E.	0,3730
jegliches weiteres UE von besonderem Interesse	N.M.E.	0,9927	>0,9999	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	0,9997	N.M.E.	0,9938
Endpunkte Verträglichkeit(2) – UE auf SOC/PT-Ebene											
UE Pyrexie (PT)	0,2358	0,7901	0,584	0,9995	0,1381	0,1729	0,2525	0,3439	0,2918	N.M.E.	0,8609
UE Periphere Ödeme (PT)	0,7375	0,5632	0,6702	0,6183	0,5568	0,9485	0,8036	0,9783	0,3014	N.M.E.	0,3079
UE Schüttelfrost (PT)	N.M.E.	0,9997	>0,9999	N.M.E.	N.M.E.	>0,9999	N.M.E.	N.M.E.	>0,9999	N.M.E.	0,9973
UE Unwohlsein (PT)	0,9093	0,9384	0,3467	0,3606	0,8121	0,6037	0,3418	0,4895	0,2325	N.M.E.	0,2877
UE Gastrointestinale Erkrankungen (SOC)	0,6311	0,5574	0,3217	0,5692	0,5063	0,9214	0,4742	0,6040	0,7536	N.M.E.	0,8055
UE Diarrhö (PT)	0,6455	0,5561	0,3494	0,3207	0,9354	0,3659	0,2879	0,7111	0,2863	N.M.E.	0,4477
UE Übelkeit (PT)	0,2405	0,8725	0,3699	0,4642	0,1178	0,6587	0,5445	0,6369	0,4307	N.M.E.	0,4591
UE Konstipation (PT)	0,1637	0,8707	0,0791	0,2603	0,6908	0,9188	0,7702	0,8930	0,2758	N.M.E.	0,9960

Endpunkte(1) Studie CA209-743	**Alters-gruppe I**	**Geschlecht**	**Ethnie I**	**Region**	**ECOG Perfor-mance Status**	**Tumor-histologie lt. IVRS**	**Krank-heits-stadium**	**Raucher-status**	**Vorherige Radio-therapie**	**Vorherige systemi-sche Therapie**	**PD-L1-Status**
UE Erbrechen (PT)	0,4196	0,6743	0,2977	0,5025	0,1670	0,1248	0,4606	0,8972	0,4282	N.M.E.	0,0851
UE Dyspnoe (PT)	0,2926	0,8506	0,9551	0,5023	0,3859	0,0898	0,5843	0,9696	0,8372	N.M.E.	0,1296
UE Husten (PT)	0,7268	0,7572	0,9159	0,7892	0,7941	0,3523	0,2828	0,8623	0,1899	N.M.E.	0,9851
UE Pleuraerguss (PT)	0,3862	0,6410	>0,9999	0,5861	0,8787	0,9911	0,7985	0,9671	0,3741	N.M.E.	0,7762
UE Pneumonitis (PT)	N.M.E.	0,9906	>0,9999	>0,9999	0,9914	0,9918	>0,9999	>0,9999	0,9914	N.M.E.	0,9935
UE Produktiver Husten (PT)	N.M.E.	0,9926	0,6617	N.M.E.	0,9570	0,8686	N.M.E.	0,7799	0,9994	N.M.E.	0,9922
UE Epistaxis (PT)	0,9514	0,9897	>0,9999	0,7573	0,3724	0,4937	0,9265	0,9751	0,9997	N.M.E.	0,9577
UE Schluckauf (PT)	0,8175	0,9993	0,9864	0,9919	0,9902	0,9887	0,5515	>0,9999	0,9991	N.M.E.	0,9937
UE Rhinorrhö (PT)	N.M.E.	N.M.E.	>0,9999	>0,9999	N.M.E.	0,9948	N.M.E.	N.M.E.	0,9965	N.M.E.	0,9950
UE Erkrankungen der Haut und des Unterhautgewebes (SOC)	0,6243	**0,0001***	0,1934	**0,0418***	0,5442	0,0875	0,7205	0,3342	0,6938	N.M.E.	0,0693
UE Pruritus (PT)	0,2300	0,9873	0,9998	>0,9999	0,9787	0,9039	0,4785	0,5629	0,5536	N.M.E.	0,6683
UE Ausschlag (PT)	0,1938	**0,0180***	0,1970	0,2332	0,7746	0,2881	0,2828	0,8617	0,9845	N.M.E.	**0,0272***
UE Alopezie (PT)	N.M.E.	N.M.E.	>0,9999	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	0,9927	N.M.E.	0,9930
UE Infektionen und parasitäre Erkrankungen (SOC)	0,2653	0,4971	0,2445	0,4194	0,5921	0,8389	0,7318	0,4507	0,4838	N.M.E.	0,6277
UE Verminderter Appetit (PT)	0,7748	0,8355	0,9427	0,8590	0,7325	0,3477	0,3271	0,8732	0,2465	N.M.E.	0,3611

Endpunkte(1) Studie CA209-743	**Alters-gruppe I**	**Geschlecht**	**Ethnie I**	**Region**	**ECOG Perfor-mance Status**	**Tumor-histologie lt. IVRS**	**Krank-heits-stadium**	**Raucher-status**	**Vorherige Radio-therapie**	**Vorherige systemi-sche Therapie**	**PD-L1-Status**
UE Hypomagnesiämie (PT)	N.M.E.	0,9921	>0,9999	N.M.E.	0,9897	0,9920	N.M.E.	N.M.E.	0,9920	N.M.E.	0,1933
UE Skelettmuskulatur-, Bindegewebs- und Knochen-erkrankungen (SOC)	**0,0195***	0,6865	0,3252	0,3526	0,8913	0,9284	0,1766	0,3803	0,2537	N.M.E.	0,5122
UE Arthralgie (PT)	0,7341	0,6344	0,7739	0,8245	0,9612	0,3103	0,7231	0,8925	0,9894	N.M.E.	0,7920
UE Myalgie (PT)	0,5191	0,7567	0,8879	>0,9999	0,9786	0,5154	0,9040	0,6764	0,9080	N.M.E.	0,8136
UE Lipase erhöht (PT)	0,6769	0,9912	0,4079	0,9526	0,3740	0,8009	0,9557	0,9640	0,9919	N.M.E.	0,2390
UE Amylase erhöht (PT)	0,8943	0,9910	0,2515	0,9609	0,5764	0,0521	0,7882	0,9738	0,9996	N.M.E.	0,9082
UE Alanin-Aminotransferase erhöht (PT)	0,8159	0,3348	>0,9999	0,8432	0,9719	0,8625	>0,9999	0,6971	0,9876	N.M.E.	0,4525
UE Alkalische Phosphatase im Blut erhöht (PT)	N.M.E.	0,1595	0,1568	0,8286	0,7434	0,9910	0,9464	0,9925	0,9924	N.M.E.	0,6752
UE Aspartat-Aminotransferase erhöht (PT)	N.M.E.	0,9914	>0,9999	N.M.E.	N.M.E.	0,9918	>0,9999	N.M.E.	0,9995	N.M.E.	0,9909
UE Dysgeusie (PT)	0,2923	0,7921	0,2746	0,3105	0,4359	0,2377	0,3762	0,3645	0,7927	N.M.E.	0,3354
UE Periphere Neuropathie (PT)	N.M.E.	0,9927	>0,9999	N.M.E.	0,9890	0,9993	N.M.E.	0,7067	0,9893	N.M.E.	0,9922

Endpunkte[1] Studie CA209-743	**Alters-gruppe I**	**Geschlecht**	**Ethnie I**	**Region**	**ECOG Perfor-mance Status**	**Tumor-histologie lt. IVRS**	**Krank-heits-stadium**	**Raucher-status**	**Vorherige Radio-therapie**	**Vorherige systemi-sche Therapie**	**PD-L1-Status**
UE Erkrankungen des Blutes und des Lymphsystems (SOC)	0,2985	0,9519	0,3204	0,2650	0,6417	0,7000	0,5121	0,7647	0,1741	N.M.E.	0,3982
UE Anämie (PT)	0,0622	0,1746	0,9829	0,2559	0,2427	0,3489	0,8674	0,7818	0,3876	N.M.E.	0,4823
UE Neutropenie (PT)	0,9376	0,5806	0,9447	0,9862	0,1839	0,3949	0,995	0,9993	0,1049	N.M.E.	0,5601
UE Thrombozytopenie (PT)	0,6472	0,4515	0,9702	0,9548	0,5220	0,9414	0,8138	0,9599	0,1840	N.M.E.	0,9629
UE Leukopenie (PT)	>0,9999	0,9998	>0,9999	>0,9999	>0,9999	>0,9999	>0,9999	>0,9999	0,9975	N.M.E.	0,9998
UE Endokrine Erkrankungen (SOC)	0,6136	0,5675	0,9249	0,8689	0,7921	0,6097	0,9946	0,7391	0,9870	N.M.E.	0,9213
UE Hypothyreose (PT)	0,8754	0,9896	0,9999	0,8521	0,6497	0,9897	0,9659	0,5774	0,9903	N.M.E.	0,9895
UE Hyperthyreose (PT)	N.M.E.	0,9934	>0,9999	N.M.E.	N.M.E.	0,9930	N.M.E.	N.M.E.	0,9936	N.M.E.	0,4728
UE Verletzungen, Vergiftungen und durch Eingriffe bedingte Komplikationen (SOC)	0,7686	0,7971	0,9440	0,9875	0,8887	0,5860	0,9463	0,1068	0,9860	N.M.E.	0,6391
UE Infusionsbedingte Reaktion (PT)	>0,9999	0,4101	>0,9999	>0,9999	0,8958	0,9915	>0,9999	0,3533	0,9920	N.M.E.	0,3379

Endpunkte(1) Studie CA209-743	**Alters-gruppe I**	**Geschlecht**	**Ethnie I**	**Region**	**ECOG Perfor-mance Status**	**Tumor-histologie lt. IVRS**	**Krank-heits-stadium**	**Raucher-status**	**Vorherige Radio-therapie**	**Vorherige systemi-sche Therapie**	**PD-L1-Status**
UE Herz-Kreislauf-Erkrankungen (SOC)	0,0692	0,5741	0,9080	0,9733	0,3104	0,3330	0,9425	0,9805	0,1130	N.M.E.	**0,0400***
UE Hepatobiläre Erkrankung (SOC)	0,1818	0,9835	0,2815	0,6976	0,9130	0,4891	0,9041	0,9500	0,9900	N.M.E.	0,0694
UE Augenerkankungen (SOC)	0,3712	0,3798	0,6063	0,5229	0,2133	0,6676	0,5629	0,4140	0,3172	N.M.E.	0,4103
UE Lakrimation erhöht (PT)	N.M.E.	0,9923	>0,9999	>0,9999	0,9917	0,9941	>0,9999	>0,9999	0,9931	N.M.E.	0,9930
UE Untersuchungen Grad ≥ 3 (SOC)	0,9949	0,2510	0,4135	0,6590	0,3935	0,2171	0,5253	0,5540	0,9888	N.M.E.	0,8214
UE Lipase erhöht Grad ≥ 3 (PT)	0,9999	0,9907	>0,9999	>0,9999	0,9912	0,9906	>0,9999	>0,9999	0,9917	N.M.E.	0,9933
UE Asthenie Grad ≥ 3 (PT)	N.M.E.	0,9913	>0,9999	0,9895	0,9894	0,9134	N.M.E.	N.M.E.	0,7619	N.M.E.	0,9891
UE Erkrankungen des Blutes und des Lymphsystems Grad ≥ 3 (SOC)	0,1376	0,9637	0,0547	**0,0398***	0,4754	0,9619	0,9735	0,8934	0,4188	N.M.E.	0,3523
UE Anämie Grad ≥ 3 (PT)	0,2683	0,5640	0,1181	0,1513	0,4703	0,5681	0,8212	0,1621	0,8575	N.M.E.	0,8369
UE Neutropenie Grad ≥ 3 (PT)	0,7698	0,9318	0,7187	0,6872	0,3896	0,8450	0,9874	0,9999	0,5894	N.M.E.	0,7639
UE Thrombozytopenie Grad ≥ 3 (PT)	N.M.E.	0,8620	0,6965	0,5924	N.M.E.	0,9534	N.M.E.	N.M.E.	0,9997	N.M.E.	0,5431

Endpunkte(1) Studie CA209-743	**Alters-gruppe I**	**Geschlecht**	**Ethnie I**	**Region**	**ECOG Perfor-mance Status**	**Tumor-histologie lt. IVRS**	**Krank-heits-stadium**	**Raucher-status**	**Vorherige Radio-therapie**	**Vorherige systemi-sche Therapie**	**PD-L1-Status**
UE Hepatobiliäre Erkrankung Grad ≥ 3 (SOC)	>0,9999	>0,9999	>0,9999	N.M.E.	>0,9999	0,9999	N.M.E.	>0,9999	0,9999	N.M.E.	0,9998
UE Erkrankungen des Nervensystems Grad ≥ 3 (SOC)	N.M.E.	0,1696	>0,9999	N.M.E.	0,5466	0,4173	0,9927	>0,9999	0,9932	N.M.E.	0,9926
UE Erkrankungen der Haut und des Unterhautgewebes Grad ≥ 3 (SOC)	N.M.E.	0,9885	>0,9999	N.M.E.	0,9908	0,9915	N.M.E.	>0,9999	0,9996	N.M.E.	0,9931
UE Erkrankungen des Muskel-Skelett-Systems und des Bindegewebes Grad ≥ 3 (SOC)	N.M.E.	0,9908	0,5746	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	0,9997	N.M.E.	0,9930
SUE Erkrankungen der Atemwege, des Brustkorbs und des Mediastinums (SOC)	0,6922	**0,0228***	0,4743	0,1956	0,2883	0,4242	0,4587	0,6731	0,6074	N.M.E.	0,2216
SUE Hepatobiliäre Erkrankungen (PT)	>0,9999	>0,9999	>0,9999	N.M.E.	>0,9999	>0,9999	N.M.E.	>0,9999	0,9979	N.M.E.	0,9997
SUE Erkrankungen des Nervensystems (SOC)	>0,9999	0,9923	>0,9999	N.M.E.	0,9911	0,9913	N.M.E.	>0,9999	0,9915	N.M.E.	0,9933
SUE Nieren- und Harnwegs-erkrankungen (SOC)	N.M.E.	0,9935	0,7413	N.M.E.	N.M.E.	**0,0486***	>0,9999	N.M.E.	0,2483	N.M.E.	0,9995

Endpunkte(1) Studie CA209-743	**Alters-gruppe I**	**Geschlecht**	**Ethnie I**	**Region**	**ECOG Perfor-mance Status**	**Tumor-histologie lt. IVRS**	**Krank-heits-stadium**	**Raucher-status**	**Vorherige Radio-therapie**	**Vorherige systemi-sche Therapie**	**PD-L1-Status**
SUE Endokrine Erkrankungen (SOC)	N.M.E.	0,9995	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	N.M.E.	0,9949	N.M.E.	0,9996
SUE Erkrankungen des Blutes und des Lymphsystems (SOC)	N.M.E.	0,5643	0,9999	0,8464	0,0989	0,5304	0,9673	0,9996	0,9902	N.M.E.	0,5131

AESI = adverse event(s) of special interest; ECOG = Eastern Cooperative Oncology Group; IVRS = Interactive Voice Recognition System; LCSS-Meso = Lung Cancer Symptom Scale - Mesothelioma adaptation; n.d. = Subgruppenanalyse nicht durchgeführt, da in keiner der Subgruppen mindestens 10 Ereignisse aufgetreten sind; PD-L1 = Programmed Death Ligand-1; PT = Preferred Term; SOC = Systemorganklasse; SUE = Schwerwiegende(s) unerwünschte(s) Ereignis(se); UE = Unerwünschte(s) Ereignis(se)

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

(2) Zeit bis zum ersten Auftreten des UE

Anhang 4-G 4.2.1: Subgruppenanalysen für Endpunkte spezifische immunvermittelte UE aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Subgroup Time-Adjusted Analyses of Immune-mediated Adverse Events
on Hazard Ratio for Any IMAEs
All Treated Subjects

Immune-Mediated Adverse Events Category: ANY IMMUNE-MEDIATED ADVERSE EVENTS

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI](mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	128 (42.7)	12.02 (8.90, 20.76)	284	6 (2.1)	N.A. (N.A., N.A.)	21.041 (9.243, 47.898) <0.0001	
AGE CATEGORIZATION								0.5219
< 65	71	25 (35.2)	20.76 (9.33, N.A.)	87	1 (1.1)	N.A. (N.A., N.A.)	32.264 (4.346, 239.535) <0.0001	
>= 65 AND < 75	151	70 (46.4)	10.94 (7.89, 20.76)	123	2 (1.6)	N.A. (N.A., N.A.)	28.700 (7.000, 117.669) <0.0001	
>= 75	78	33 (42.3)	19.09 (4.53, N.A.)	74	3 (4.1)	N.A. (N.A., N.A.)	11.339 (3.456, 37.207) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimhr-ebr2252.sas 04FEB2021:12:51:04

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Subgroup Time-Adjusted Analyses of Immune-mediated Adverse Events
on Hazard Ratio for Any IMAEs
All Treated Subjects

Immune-Mediated Adverse Events Category: ANY IMMUNE-MEDIATED ADVERSE EVENTS

Immune-mediated Adverse Events	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								0.8342
MALE	232	100 (43.1)	17.58 (8.77, 21.68)	221	5 (2.3)	N.A. (N.A., N.A.)	20.609 (8.366, 50.770) <0.0001	
FEMALE	68	28 (41.2)	10.94 (7.89, N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	23.605 (3.170, 175.781) <0.0001	
RACE								0.9995
WHITE	263	111 (42.2)	17.58 (9.33, 20.76)	233	6 (2.6)	N.A. (N.A., N.A.)	16.419 (7.187, 37.509) <0.0001	
ASIAN	26	12 (46.2)	10.94 (2.07, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. <0.0001	
OTHER	11	5 (45.5)	5.68 (2.04, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.0019	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Immune-mediated Adverse Events
on Hazard Ratio for Any IMAEs
All Treated Subjects

Immune-Mediated Adverse Events Category: ANY IMMUNE-MEDIATED ADVERSE EVENTS

Immune-mediated Adverse Events	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								0.6277
NORTH AMERICA	32	17 (53.1)	8.77 (2.79, 20.76)	25	2 (8.0)	N.A. (N.A., N.A.)	5.563 (1.253, 24.690) 0.0109	
EUROPE	175	74 (42.3)	17.58 (9.33, 21.68)	164	3 (1.8)	N.A. (N.A., N.A.)	22.769 (7.141, 72.602) <0.0001	
ASIA	26	12 (46.2)	10.94 (2.07, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. <0.0001	
REST OF WORLD	67	25 (37.3)	N.A. (5.52, N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	25.554 (3.447, 189.443) <0.0001	
ECOG PERFORMANCE STATUS								0.9605
0	113	56 (49.6)	8.77 (5.22, N.A.)	121	3 (2.5)	N.A. (N.A., N.A.)	22.294 (6.944, 71.577) <0.0001	
>= 1	187	72 (38.5)	17.61 (10.58, N.A.)	163	3 (1.8)	N.A. (N.A., N.A.)	20.635 (6.465, 65.862) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Immune-mediated Adverse Events
on Hazard Ratio for Any IMAEs
All Treated Subjects

Immune-Mediated Adverse Events Category: ANY IMMUNE-MEDIATED ADVERSE EVENTS

Immune-mediated Adverse Events	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
IVRS HISTOLOGY								0.6177
EPITHELIOID	233	98 (42.1)	17.58 (9.33, 20.76)	219	5 (2.3)	N.A. (N.A., N.A.)	18.237 (7.386, 45.031) <0.0001	
NON-EPITHELIOID	67	30 (44.8)	10.94 (4.14, N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	35.625 (4.843, 262.064) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Immune-mediated Adverse Events
on Hazard Ratio for Any IMAEs
All Treated Subjects

Immune-Mediated Adverse Events Category: ANY IMMUNE-MEDIATED ADVERSE EVENTS

Immune-mediated Adverse Events	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 STUDY ENTRY								0.9687
STAGE I	12	5 (41.7)	N.A. (0.53, N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. 0.0027	
STAGE II	23	10 (43.5)	21.68 (3.35, N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.0016	
STAGE III	102	47 (46.1)	10.94 (5.78, N.A.)	101	2 (2.0)	N.A. (N.A., N.A.)	24.007 (5.792, 99.505) <0.0001	
STAGE IV	158	64 (40.5)	17.61 (8.77, N.A.)	140	4 (2.9)	N.A. (N.A., N.A.)	14.080 (5.093, 38.919) <0.0001	
NOT REPORTED	5	2 (40.0)	N.A. (0.49, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Immune-mediated Adverse Events
on Hazard Ratio for Any IMAEs
All Treated Subjects

Immune-Mediated Adverse Events Category: ANY IMMUNE-MEDIATED ADVERSE EVENTS

Immune-mediated Adverse Events	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
TOBACCO USE								0.4816
NEVER	124	44 (35.5)	12.02 (10.58, N.A.)	116	2 (1.7)	N.A. (N.A., N.A.)	19.764 (4.752, 82.205) <0.0001	
FORMER	155	73 (47.1)	10.94 (5.06, 21.68)	153	3 (2.0)	N.A. (N.A., N.A.)	27.190 (8.535, 86.621) <0.0001	
CURRENT	18	10 (55.6)	8.77 (1.91, N.A.)	8	1 (12.5)	N.A. (1.25, N.A.)	4.062 (0.507, 32.526) 0.1532	
UNKNOWN	3	1 (33.3)	N.A. (3.65, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	
PRIOR RADIOTHERAPY								0.9851
YES	28	6 (21.4)	N.A. (17.58, N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.0295	
NO	272	122 (44.9)	10.94 (8.05, 20.76)	258	6 (2.3)	N.A. (N.A., N.A.)	20.508 (9.001, 46.725) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubimhr-ebr2252.sas 04FEB2021:12:51:04

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Subgroup Time-Adjusted Analyses of Immune-mediated Adverse Events
on Hazard Ratio for Any IMAEs
All Treated Subjects

Immune-Mediated Adverse Events Category: ANY IMMUNE-MEDIATED ADVERSE EVENTS

Immune-mediated Adverse Events Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI](mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	128 (42.8)	N.M.E.	284	6 (2.1)	N.M.E.	N.M.E.	
PD-L1								0.8110
POSITIVE	229	103 (45.0)	10.94 (7.89, 20.76)	203	5 (2.5)	N.A. (N.A., N.A.)	19.230 (7.808, 47.358) <0.0001	
NEGATIVE	57	19 (33.3)	17.61 (8.77, N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	22.194 (2.915, 168.966) <0.0001	
NOT REPORTED	14	6 (42.9)	N.A. (3.15, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Anhang 4-G 4.2.2: Subgruppenanalysen für Endpunkte spezifische UE (select UE) aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	236 (78.7)	1.48 (1.22, 1.87)	284	107 (37.7)	N.A. (N.A., N.A.)	2.789 (2.212, 3.517) <0.0001	
AGE CATEGORIZATION								0.5602
< 65	71	53 (74.6)	1.35 (0.69, 2.99)	87	30 (34.5)	N.A. (N.A., N.A.)	2.880 (1.826, 4.544) <0.0001	
>= 65 AND < 75	151	115 (76.2)	1.87 (1.45, 2.73)	123	46 (37.4)	N.A. (N.A., N.A.)	2.510 (1.773, 3.553) <0.0001	
>= 75	78	68 (87.2)	0.94 (0.56, 1.48)	74	31 (41.9)	N.A. (2.86, N.A.)	3.273 (2.128, 5.032) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI](mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0821
MALE	232	184 (79.3)	1.41 (0.92, 1.77)	221	80 (36.2)	N.A. (N.A., N.A.)	3.132 (2.399, 4.088) <0.0001	
FEMALE	68	52 (76.5)	2.53 (1.41, 3.94)	63	27 (42.9)	N.A. (2.86, N.A.)	1.918 (1.194, 3.079) 0.0061	
RACE								0.1068
WHITE	263	208 (79.1)	1.45 (1.22, 1.91)	233	94 (40.3)	N.A. (N.A., N.A.)	2.562 (2.002, 3.280) <0.0001	
ASIAN	26	21 (80.8)	0.48 (0.23, 1.84)	38	12 (31.6)	N.A. (6.21, N.A.)	3.769 (1.823, 7.795) 0.0001	
OTHER	11	7 (63.6)	3.71 (0.89, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	14.450 (1.726, 120.994) 0.0015	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubslhr-ebr2252.sas 04FEB2021:12:57:58

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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.2287
NORTH AMERICA	32	30 (93.8)	0.49 (0.36, 1.18)	25	12 (48.0)	6.01 (0.85, N.A.)	3.761 (1.852, 7.637) <0.0001	
EUROPE	175	135 (77.1)	2.10 (1.45, 3.19)	164	63 (38.4)	N.A. (N.A., N.A.)	2.357 (1.740, 3.193) <0.0001	
ASIA	26	21 (80.8)	0.48 (0.23, 1.84)	38	12 (31.6)	N.A. (6.21, N.A.)	3.769 (1.823, 7.795) 0.0001	
REST OF WORLD	67	50 (74.6)	1.41 (0.76, 1.91)	57	20 (35.1)	N.A. (N.A., N.A.)	3.415 (2.021, 5.770) <0.0001	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.6899
0	113	92 (81.4)	1.41 (0.95, 2.37)	121	49 (40.5)	N.A. (4.67, N.A.)	2.772 (1.952, 3.937) <0.0001	
>= 1	187	144 (77.0)	1.48 (1.08, 1.91)	163	58 (35.6)	N.A. (N.A., N.A.)	2.818 (2.067, 3.842) <0.0001	
IVRS HISTOLOGY								0.0440**
EPITHELIOID	233	182 (78.1)	1.58 (1.35, 2.37)	219	87 (39.7)	N.A. (N.A., N.A.)	2.499 (1.929, 3.238) <0.0001	
NON-EPITHELIOID	67	54 (80.6)	1.08 (0.49, 1.84)	65	20 (30.8)	N.A. (N.A., N.A.)	4.156 (2.461, 7.019) <0.0001	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9969
STAGE I	12	10 (83.3)	2.14 (0.49, 4.63)	17	7 (41.2)	N.A. (0.99, N.A.)	2.746 (1.032, 7.306) 0.0351	
STAGE II	23	19 (82.6)	1.08 (0.53, 3.19)	21	10 (47.6)	N.A. (2.00, N.A.)	2.587 (1.183, 5.659) 0.0135	
STAGE III	102	82 (80.4)	1.58 (0.99, 2.53)	101	37 (36.6)	N.A. (N.A., N.A.)	2.871 (1.934, 4.262) <0.0001	
STAGE IV	158	120 (75.9)	1.45 (1.08, 1.91)	140	51 (36.4)	N.A. (N.A., N.A.)	2.759 (1.980, 3.846) <0.0001	
NOT REPORTED	5	5 (100.0)	0.13 (0.03, 3.78)	5	2 (40.0)	N.A. (0.49, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.7224
NEVER	124	94 (75.8)	1.81 (1.31, 3.02)	116	39 (33.6)	N.A. (N.A., N.A.)	2.916 (1.997, 4.257) <0.0001	
FORMER	155	124 (80.0)	1.35 (0.79, 1.77)	153	63 (41.2)	N.A. (6.01, N.A.)	2.660 (1.953, 3.622) <0.0001	
CURRENT	18	15 (83.3)	2.32 (0.89, 4.76)	8	2 (25.0)	N.A. (0.62, N.A.)	4.449 (1.012, 19.556) 0.0311	
UNKNOWN	3	3 (100.0)	0.30 (0.07, 0.95)	7	3 (42.9)	N.A. (0.03, N.A.)	4.164 (0.673, 25.747) 0.0985	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI](mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.8302
YES	28	21 (75.0)	1.91 (0.92, 3.71)	26	9 (34.6)	N.A. (2.89, N.A.)	2.822 (1.284, 6.201) 0.0070	
NO	272	215 (79.0)	1.41 (1.08, 1.81)	258	98 (38.0)	N.A. (N.A., N.A.)	2.786 (2.185, 3.551) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	235 (78.6)	N.M.E.	284	107 (37.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Select Adverse Events
on Hazard Ratio for Any Select AEs
All Treated Subjects

Select Adverse Events Category: ANY SELECT ADVERSE EVENTS

Select Adverse Events / Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI](mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI](mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3730
POSITIVE	229	183 (79.9)	1.41 (0.95, 1.81)	203	73 (36.0)	N.A. (N.A., N.A.)	3.062 (2.325, 4.032) <0.0001	
NEGATIVE	57	42 (73.7)	1.58 (0.89, 4.17)	76	30 (39.5)	N.A. (3.65, N.A.)	2.351 (1.462, 3.780) 0.0003	
NOT REPORTED	14	11 (78.6)	2.99 (0.53, 3.98)	5	4 (80.0)	1.02 (0.03, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Anhang 4-G 4.2.3: Subgruppenanalysen für Endpunkte weitere UE von besonderem Interesse (OESI) aus CA209-743 – Zeit bis zum ersten Auftreten des UE

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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
OVERALL	300	13 (4.3)	N.A. (N.A., N.A.)	284	1 (0.4)	N.A. (N.A., N.A.)	7.934 (0.996, 63.206) 0.0205	
AGE CATEGORIZATION								N.M.E.
< 65	71	2 (2.8)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	8 (5.3)	N.M.E.	123	0	N.M.E.	N.M.E.	
>= 75	78	3 (3.8)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								0.9927
MALE	232	12 (5.2)	N.A. (N.A., N.A.)	221	1 (0.5)	N.A. (N.A., N.A.)	7.012 (0.867, 56.740) 0.0339	
FEMALE	68	1 (1.5)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.3364	
RACE								>0.9999
WHITE	263	12 (4.6)	N.A. (N.A., N.A.)	233	0	N.A. (N.A., N.A.)	N.M.E. 0.0069	
ASIAN	26	1 (3.8)	N.A. (10.55, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.4543	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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								N.M.E.
NORTH AMERICA	32	1 (3.1)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	7 (4.0)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	1 (3.8)	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
REST OF WORLD	67	4 (6.0)	N.M.E.	57	0	N.M.E.	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 PERFORMANCE STATUS								N.M.E.
0	113	6 (5.3)	N.M.E.	121	0	N.M.E.	N.M.E.	
>= 1	187	7 (3.7)	N.M.E.	163	1 (0.6)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								N.M.E.
EPITHELIOID	233	9 (3.9)	N.M.E.	219	0	N.M.E.	N.M.E.	
NON-EPITHELIOID	67	4 (6.0)	N.M.E.	65	1 (1.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 STUDY ENTRY								N.M.E.
STAGE I	12	1 (8.3)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	1 (4.3)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	6 (5.9)	N.M.E.	101	1 (1.0)	N.M.E.	N.M.E.	
STAGE IV	158	5 (3.2)	N.M.E.	140	0	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
TOBACCO USE								N.M.E.
NEVER	124	3 (2.4)	N.M.E.	116	1 (0.9)	N.M.E.	N.M.E.	
FORMER	155	9 (5.8)	N.M.E.	153	0	N.M.E.	N.M.E.	
CURRENT	18	0	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	1 (33.3)	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsuboesihr-ebr2252.sas 04FEB2021:12:54:35

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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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 RADIOTHERAPY								0.9997
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	13 (4.8)	N.A. (N.A., N.A.)	258	1 (0.4)	N.A. (N.A., N.A.)	8.021 (1.007, 63.893) 0.0196	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	13 (4.3)	N.M.E.	284	1 (0.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsuboesihr-ebr2252.sas 04FEB2021:12:54:35

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Subgroup Time-Adjusted Analyses of Other Events of Special Interest
on Hazard Ratio for any OESI
All Treated Subjects

Other Events of Special Interest Category: ANY OTHER EVENTS OF SPECIAL INTEREST

Other Events of Special Interest	Nivo + Ipi			Chemo			Nivo + Ipi vs. Chemo	
Subgroup	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)
PD-L1								0.9938
POSITIVE	229	9 (3.9)	N.A. (N.A., N.A.)	203	1 (0.5)	N.A. (N.A., N.A.)	3.693 (0.418, 32.618) 0.2086	
NEGATIVE	57	4 (7.0)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.0178	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo or ipi in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. Hazard Ratio is Nivo+Ipi over Chemo. (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsuboesihr-ebr2252.sas 04FEB2021:12:54:35

Anhang 4-G 4.2.4: Subgruppenanalysen für Endpunkte Unerwünschte Ereignisse auf SOC/PT-Ebene aus CA209-743 – Zeit bis zum ersten Auftreten des UE

Anhang 4-G 4.2.4.1: Subgruppenanalysen für Endpunkt Jegliches UE auf SOC/PT-Ebene aus CA209-743

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	57 (19.0)	N.A. (N.A., N.A.)	284	17 (6.0)	N.A. (N.A., N.A.)	2.788 (1.599, 4.862) 0.0002	
AGE CATEGORIZATION								0.2358
< 65	71	12 (16.9)	N.A. (N.A., N.A.)	87	7 (8.0)	N.A. (N.A., N.A.)	2.303 (0.906, 5.852) 0.0712	
>= 65 AND < 75	151	28 (18.5)	N.A. (N.A., N.A.)	123	3 (2.4)	N.A. (N.A., N.A.)	5.942 (1.766, 19.992) 0.0011	
>= 75	78	17 (21.8)	N.A. (N.A., N.A.)	74	7 (9.5)	N.A. (N.A., N.A.)	2.093 (0.846, 5.178) 0.1024	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7901
MALE	232	48 (20.7)	N.A. (N.A., N.A.)	221	15 (6.8)	N.A. (N.A., N.A.)	2.857 (1.581, 5.162) 0.0003	
FEMALE	68	9 (13.2)	N.A. (N.A., N.A.)	63	2 (3.2)	N.A. (N.A., N.A.)	2.484 (0.486, 12.698) 0.2587	
RACE								0.5840
WHITE	263	46 (17.5)	N.A. (N.A., N.A.)	233	10 (4.3)	N.A. (N.A., N.A.)	3.679 (1.834, 7.382) <0.0001	
ASIAN	26	10 (38.5)	12.42 (5.98, N.A.)	38	6 (15.8)	N.A. (N.A., N.A.)	1.872 (0.628, 5.577) 0.2524	
OTHER	11	1 (9.1)	N.A. (N.A., N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	1.255 (0.078, 20.094) 0.8721	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9995
NORTH AMERICA	32	3 (9.4)	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.1197	
EUROPE	175	30 (17.1)	N.A. (N.A., N.A.)	164	11 (6.7)	N.A. (N.A., N.A.)	2.278 (1.121, 4.627) 0.0193	
ASIA	26	10 (38.5)	12.42 (5.98, N.A.)	38	6 (15.8)	N.A. (N.A., N.A.)	1.872 (0.628, 5.577) 0.2524	
REST OF WORLD	67	14 (20.9)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.0013	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.1381
0	113	25 (22.1)	N.A. (N.A., N.A.)	121	5 (4.1)	N.A. (N.A., N.A.)	4.982 (1.879, 13.207) 0.0003	
>= 1	187	32 (17.1)	N.A. (N.A., N.A.)	163	12 (7.4)	N.A. (N.A., N.A.)	1.940 (0.975, 3.863) 0.0545	
IVRS HISTOLOGY								0.1729
EPITHELIOID	233	44 (18.9)	N.A. (N.A., N.A.)	219	10 (4.6)	N.A. (N.A., N.A.)	3.789 (1.884, 7.620) <0.0001	
NON-EPITHELIOID	67	13 (19.4)	N.A. (16.36, N.A.)	65	7 (10.8)	N.A. (N.A., N.A.)	1.371 (0.512, 3.673) 0.5306	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2525
STAGE I	12	3 (25.0)	N.A. (0.23, N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	4.899 (0.508, 47.206) 0.1278	
STAGE II	23	3 (13.0)	N.A. (12.42, N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	0.642 (0.107, 3.844) 0.6248	
STAGE III	102	21 (20.6)	N.A. (N.A., N.A.)	101	8 (7.9)	N.A. (N.A., N.A.)	2.147 (0.921, 5.004) 0.0702	
STAGE IV	158	30 (19.0)	N.A. (N.A., N.A.)	140	5 (3.6)	N.A. (N.A., N.A.)	4.819 (1.844, 12.592) 0.0004	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.3439
NEVER	124	25 (20.2)	N.A. (N.A., N.A.)	116	5 (4.3)	N.A. (N.A., N.A.)	4.165 (1.564, 11.087) 0.0019	
FORMER	155	30 (19.4)	N.A. (N.A., N.A.)	153	11 (7.2)	N.A. (N.A., N.A.)	2.346 (1.149, 4.791) 0.0159	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.30, N.A.)	0.457 (0.029, 7.314) 0.5705	
UNKNOWN	3	1 (33.3)	N.A. (0.23, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2918
YES	28	3 (10.7)	N.A. (N.A., N.A.)	26	2 (7.7)	N.A. (N.A., N.A.)	0.980 (0.146, 6.562) 0.9832	
NO	272	54 (19.9)	N.A. (N.A., N.A.)	258	15 (5.8)	N.A. (N.A., N.A.)	3.057 (1.702, 5.493) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	57 (19.1)	N.M.E.	284	17 (6.0)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Pyrexia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.8609
POSITIVE	229	46 (20.1)	N.A. (N.A., N.A.)	203	13 (6.4)	N.A. (N.A., N.A.)	2.802 (1.493, 5.261) 0.0008	
NEGATIVE	57	8 (14.0)	N.A. (N.A., N.A.)	76	4 (5.3)	N.A. (N.A., N.A.)	2.501 (0.732, 8.548) 0.1299	
NOT REPORTED	14	3 (21.4)	N.A. (7.46, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	47 (15.7)	N.A. (N.A., N.A.)	284	19 (6.7)	N.A. (N.A., N.A.)	2.287 (1.333, 3.926) 0.0020	
AGE CATEGORIZATION								0.7375
< 65	71	11 (15.5)	N.A. (N.A., N.A.)	87	4 (4.6)	N.A. (N.A., N.A.)	3.240 (1.016, 10.336) 0.0355	
>= 65 AND < 75	151	24 (15.9)	N.A. (N.A., N.A.)	123	9 (7.3)	N.A. (N.A., N.A.)	2.041 (0.935, 4.457) 0.0674	
>= 75	78	12 (15.4)	N.A. (N.A., N.A.)	74	6 (8.1)	N.A. (N.A., N.A.)	2.026 (0.760, 5.403) 0.1496	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5632
MALE	232	35 (15.1)	N.A. (N.A., N.A.)	221	13 (5.9)	N.A. (N.A., N.A.)	2.583 (1.359, 4.909) 0.0026	
FEMALE	68	12 (17.6)	N.A. (N.A., N.A.)	63	6 (9.5)	N.A. (N.A., N.A.)	1.615 (0.587, 4.444) 0.3490	
RACE								0.6702
WHITE	263	42 (16.0)	N.A. (N.A., N.A.)	233	16 (6.9)	N.A. (N.A., N.A.)	2.297 (1.283, 4.111) 0.0040	
ASIAN	26	2 (7.7)	N.A. (N.A., N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.085 (0.181, 6.506) 0.9290	
OTHER	11	3 (27.3)	N.A. (0.49, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.1228	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.6183
NORTH AMERICA	32	6 (18.8)	N.A. (9.72, N.A.)	25	3 (12.0)	N.A. (N.A., N.A.)	1.270 (0.303, 5.320) 0.7434	
EUROPE	175	27 (15.4)	N.A. (N.A., N.A.)	164	10 (6.1)	N.A. (N.A., N.A.)	2.707 (1.310, 5.594) 0.0051	
ASIA	26	2 (7.7)	N.A. (N.A., N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.085 (0.181, 6.506) 0.9290	
REST OF WORLD	67	12 (17.9)	N.A. (N.A., N.A.)	57	3 (5.3)	N.A. (N.A., N.A.)	2.785 (0.754, 10.292) 0.1088	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.5568
0	113	19 (16.8)	N.A. (N.A., N.A.)	121	7 (5.8)	N.A. (N.A., N.A.)	2.759 (1.144, 6.653) 0.0184	
>= 1	187	28 (15.0)	N.A. (N.A., N.A.)	163	12 (7.4)	N.A. (N.A., N.A.)	2.011 (1.014, 3.986) 0.0412	
IVRS HISTOLOGY								0.9485
EPITHELIOID	233	40 (17.2)	N.A. (N.A., N.A.)	219	16 (7.3)	N.A. (N.A., N.A.)	2.319 (1.290, 4.170) 0.0038	
NON-EPITHELIOID	67	7 (10.4)	N.A. (N.A., N.A.)	65	3 (4.6)	N.A. (N.A., N.A.)	2.126 (0.531, 8.508) 0.2752	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.8036
STAGE I	12	2 (16.7)	N.A. (1.64, N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. 0.0853	
STAGE II	23	4 (17.4)	N.A. (9.72, N.A.)	21	2 (9.5)	N.A. (N.A., N.A.)	1.486 (0.248, 8.916) 0.6625	
STAGE III	102	13 (12.7)	N.A. (N.A., N.A.)	101	8 (7.9)	N.A. (N.A., N.A.)	1.585 (0.648, 3.877) 0.3090	
STAGE IV	158	28 (17.7)	N.A. (N.A., N.A.)	140	9 (6.4)	N.A. (N.A., N.A.)	2.686 (1.258, 5.733) 0.0079	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9783
NEVER	124	24 (19.4)	N.A. (N.A., N.A.)	116	11 (9.5)	N.A. (N.A., N.A.)	2.009 (0.974, 4.144) 0.0540	
FORMER	155	21 (13.5)	N.A. (N.A., N.A.)	153	8 (5.2)	N.A. (N.A., N.A.)	2.536 (1.110, 5.794) 0.0222	
CURRENT	18	2 (11.1)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.3676	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.3014
YES	28	7 (25.0)	N.A. (5.22, N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	7.057 (0.867, 57.412) 0.0331	
NO	272	40 (14.7)	N.A. (N.A., N.A.)	258	18 (7.0)	N.A. (N.A., N.A.)	2.019 (1.147, 3.556) 0.0130	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	47 (15.7)	N.M.E.	284	19 (6.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Oedema Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3079
POSITIVE	229	39 (17.0)	N.A. (N.A., N.A.)	203	13 (6.4)	N.A. (N.A., N.A.)	2.545 (1.346, 4.811) 0.0029	
NEGATIVE	57	6 (10.5)	N.A. (N.A., N.A.)	76	6 (7.9)	N.A. (N.A., N.A.)	1.398 (0.451, 4.334) 0.5603	
NOT REPORTED	14	2 (14.3)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	13 (4.3)	N.A. (N.A., N.A.)	284	0	N.A. (N.A., N.A.)	N.M.E. 0.0011	
AGE CATEGORIZATION								N.M.E.
< 65	71	1 (1.4)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	7 (4.6)	N.M.E.	123	0	N.M.E.	N.M.E.	
>= 75	78	5 (6.4)	N.M.E.	74	0	N.M.E.	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9997
MALE	232	12 (5.2)	N.A. (N.A., N.A.)	221	0	N.A. (N.A., N.A.)	N.M.E. 0.0017	
FEMALE	68	1 (1.5)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.3322	
RACE								>0.9999
WHITE	263	13 (4.9)	N.A. (N.A., N.A.)	233	0	N.A. (N.A., N.A.)	N.M.E. 0.0015	
ASIAN	26	0	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	8 (25.0)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	3 (1.7)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	0	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	2 (3.0)	N.M.E.	57	0	N.M.E.	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
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(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	6 (5.3)	N.M.E.	121	0	N.M.E.	N.M.E.	
>= 1	187	7 (3.7)	N.M.E.	163	0	N.M.E.	N.M.E.	
IVRS HISTOLOGY								>0.9999
EPITHELIOID	233	10 (4.3)	N.A. (N.A., N.A.)	219	0	N.A. (N.A., N.A.)	N.M.E. 0.0035	
NON-EPITHELIOID	67	3 (4.5)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.1587	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	1 (8.3)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	1 (4.3)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	4 (3.9)	N.M.E.	101	0	N.M.E.	N.M.E.	
STAGE IV	158	7 (4.4)	N.M.E.	140	0	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	3 (2.4)	N.M.E.	116	0	N.M.E.	N.M.E.	
FORMER	155	9 (5.8)	N.M.E.	153	0	N.M.E.	N.M.E.	
CURRENT	18	1 (5.6)	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								>0.9999
YES	28	1 (3.6)	N.A. (15.15, N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	12 (4.4)	N.A. (N.A., N.A.)	258	0	N.A. (N.A., N.A.)	N.M.E. 0.0010	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	13 (4.3)	N.M.E.	284	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Chills

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Chills Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9973
POSITIVE	229	13 (5.7)	N.A. (N.A., N.A.)	203	0	N.A. (N.A., N.A.)	N.M.E. 0.0015	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	10 (3.3)	N.A. (N.A., N.A.)	284	20 (7.0)	N.A. (N.A., N.A.)	0.373 (0.165, 0.844) 0.0138	
AGE CATEGORIZATION								0.9093
< 65	71	2 (2.8)	N.A. (N.A., N.A.)	87	6 (6.9)	N.A. (N.A., N.A.)	0.201 (0.024, 1.667) 0.0985	
>= 65 AND < 75	151	6 (4.0)	N.A. (N.A., N.A.)	123	11 (8.9)	N.A. (N.A., N.A.)	0.362 (0.126, 1.043) 0.0496	
>= 75	78	2 (2.6)	N.A. (N.A., N.A.)	74	3 (4.1)	N.A. (N.A., N.A.)	0.629 (0.105, 3.765) 0.6099	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9384
MALE	232	8 (3.4)	N.A. (N.A., N.A.)	221	16 (7.2)	N.A. (N.A., N.A.)	0.353 (0.139, 0.896) 0.0221	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	4 (6.3)	N.A. (N.A., N.A.)	0.451 (0.083, 2.463) 0.3452	
RACE								0.3467
WHITE	263	7 (2.7)	N.A. (N.A., N.A.)	233	8 (3.4)	N.A. (N.A., N.A.)	0.560 (0.185, 1.698) 0.2989	
ASIAN	26	2 (7.7)	N.A. (N.A., N.A.)	38	12 (31.6)	N.A. (5.59, N.A.)	0.214 (0.048, 0.957) 0.0267	
OTHER	11	1 (9.1)	N.A. (4.37, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.2410	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.3606
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
EUROPE	175	7 (4.0)	N.A. (N.A., N.A.)	164	6 (3.7)	N.A. (N.A., N.A.)	0.940 (0.305, 2.898) 0.9139	
ASIA	26	2 (7.7)	N.A. (N.A., N.A.)	38	12 (31.6)	N.A. (5.59, N.A.)	0.214 (0.048, 0.957) 0.0267	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	2 (3.5)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.1355	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.8121
0	113	3 (2.7)	N.A. (N.A., N.A.)	121	6 (5.0)	N.A. (N.A., N.A.)	0.528 (0.132, 2.109) 0.3576	
>= 1	187	7 (3.7)	N.A. (N.A., N.A.)	163	14 (8.6)	N.A. (N.A., N.A.)	0.307 (0.111, 0.846) 0.0158	
IVRS HISTOLOGY								0.6037
EPITHELIOID	233	7 (3.0)	N.A. (N.A., N.A.)	219	12 (5.5)	N.A. (N.A., N.A.)	0.391 (0.139, 1.098) 0.0648	
NON-EPITHELIOID	67	3 (4.5)	N.A. (N.A., N.A.)	65	8 (12.3)	N.A. (N.A., N.A.)	0.352 (0.093, 1.327) 0.1077	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.3418
STAGE I	12	2 (16.7)	N.A. (3.02, N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	3.671 (0.328, 41.116) 0.2593	
STAGE II	23	0	N.A. (N.A., N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	N.M.E. 0.0689	
STAGE III	102	4 (3.9)	N.A. (N.A., N.A.)	101	5 (5.0)	N.A. (N.A., N.A.)	0.578 (0.138, 2.420) 0.4474	
STAGE IV	158	4 (2.5)	N.A. (N.A., N.A.)	140	11 (7.9)	N.A. (N.A., N.A.)	0.238 (0.068, 0.836) 0.0152	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.4895
NEVER	124	5 (4.0)	N.A. (N.A., N.A.)	116	4 (3.4)	N.A. (N.A., N.A.)	1.200 (0.322, 4.471) 0.7855	
FORMER	155	5 (3.2)	N.A. (N.A., N.A.)	153	15 (9.8)	N.A. (N.A., N.A.)	0.200 (0.060, 0.664) 0.0037	
CURRENT	18	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.10, N.A.)	N.M.E. 0.1336	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2325
YES	28	2 (7.1)	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	1.878 (0.170, 20.718) 0.6011	
NO	272	8 (2.9)	N.A. (N.A., N.A.)	258	19 (7.4)	N.A. (N.A., N.A.)	0.296 (0.119, 0.736) 0.0054	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	10 (3.3)	N.M.E.	284	20 (7.0)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Malaise

Adverse Events with SOC: General Disorders and Administration Site Conditions and PT: Malaise Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.2877
POSITIVE	229	7 (3.1)	N.A. (N.A., N.A.)	203	15 (7.4)	N.A. (N.A., N.A.)	0.288 (0.106, 0.785) 0.0096	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	4 (5.3)	N.A. (N.A., N.A.)	1.024 (0.229, 4.576) 0.9757	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (0.16, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	190 (63.3)	4.17 (3.22, 6.37)	284	191 (67.3)	0.85 (0.66, 1.38)	0.605 (0.491, 0.747) <0.0001	
AGE CATEGORIZATION								0.6311
< 65	71	43 (60.6)	6.34 (2.76, 10.58)	87	61 (70.1)	0.92 (0.16, 1.45)	0.490 (0.325, 0.739) 0.0006	
>= 65 AND < 75	151	98 (64.9)	4.11 (2.73, 7.46)	123	81 (65.9)	0.85 (0.66, 2.37)	0.642 (0.472, 0.874) 0.0051	
>= 75	78	49 (62.8)	3.75 (1.64, 7.46)	74	49 (66.2)	0.82 (0.30, 1.87)	0.685 (0.457, 1.028) 0.0704	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5574
MALE	232	144 (62.1)	4.93 (3.35, 6.80)	221	148 (67.0)	0.82 (0.49, 1.41)	0.581 (0.457, 0.738) <0.0001	
FEMALE	68	46 (67.6)	3.29 (0.82, 8.51)	63	43 (68.3)	0.89 (0.36, 1.87)	0.706 (0.457, 1.090) 0.1170	
RACE								0.3217
WHITE	263	166 (63.1)	4.21 (3.35, 6.70)	233	151 (64.8)	1.05 (0.76, 2.04)	0.648 (0.515, 0.815) 0.0002	
ASIAN	26	19 (73.1)	2.83 (0.62, 11.76)	38	31 (81.6)	0.11 (0.10, 0.49)	0.461 (0.250, 0.849) 0.0131	
OTHER	11	5 (45.5)	N.A. (0.49, N.A.)	13	9 (69.2)	1.02 (0.16, N.A.)	0.425 (0.141, 1.287) 0.1191	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5692
NORTH AMERICA	32	20 (62.5)	5.55 (1.41, 19.88)	25	19 (76.0)	0.69 (0.13, 4.17)	0.465 (0.239, 0.907) 0.0223	
EUROPE	175	108 (61.7)	5.09 (3.75, 7.56)	164	100 (61.0)	1.45 (0.89, 2.46)	0.672 (0.505, 0.892) 0.0061	
ASIA	26	19 (73.1)	2.83 (0.62, 11.76)	38	31 (81.6)	0.11 (0.10, 0.49)	0.461 (0.250, 0.849) 0.0131	
REST OF WORLD	67	43 (64.2)	2.76 (1.58, 6.37)	57	41 (71.9)	0.72 (0.13, 1.48)	0.615 (0.396, 0.955) 0.0312	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.5063
0	113	74 (65.5)	4.01 (2.53, 7.46)	121	79 (65.3)	0.92 (0.49, 1.87)	0.656 (0.472, 0.914) 0.0135	
>= 1	187	116 (62.0)	5.09 (2.99, 7.20)	163	112 (68.7)	0.82 (0.36, 1.41)	0.572 (0.436, 0.751) <0.0001	
IVRS HISTOLOGY								0.9214
EPITHELIOID	233	144 (61.8)	5.09 (3.88, 7.46)	219	141 (64.4)	0.92 (0.72, 1.71)	0.615 (0.482, 0.783) <0.0001	
NON-EPITHELIOID	67	46 (68.7)	2.63 (1.18, 5.55)	65	50 (76.9)	0.30 (0.13, 1.41)	0.579 (0.382, 0.880) 0.0105	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.4742
STAGE I	12	8 (66.7)	2.83 (0.43, N.A.)	17	12 (70.6)	1.41 (0.13, N.A.)	0.805 (0.328, 1.974) 0.6432	
STAGE II	23	12 (52.2)	7.56 (3.22, N.A.)	21	16 (76.2)	0.72 (0.10, 2.27)	0.396 (0.179, 0.880) 0.0194	
STAGE III	102	64 (62.7)	6.37 (2.46, 9.82)	101	66 (65.3)	0.72 (0.20, 2.07)	0.603 (0.420, 0.867) 0.0064	
STAGE IV	158	102 (64.6)	3.94 (2.63, 6.34)	140	94 (67.1)	0.92 (0.56, 1.48)	0.626 (0.468, 0.838) 0.0018	
NOT REPORTED	5	4 (80.0)	3.12 (0.07, 7.59)	5	3 (60.0)	0.80 (0.20, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.6040
NEVER	124	69 (55.6)	7.56 (3.88, 10.58)	116	79 (68.1)	0.95 (0.72, 2.14)	0.500 (0.355, 0.705) <0.0001	
FORMER	155	108 (69.7)	3.19 (2.07, 4.07)	153	104 (68.0)	0.72 (0.30, 1.38)	0.705 (0.534, 0.931) 0.0164	
CURRENT	18	11 (61.1)	9.72 (3.29, 14.19)	8	4 (50.0)	N.A. (0.03, N.A.)	0.542 (0.160, 1.840) 0.3188	
UNKNOWN	3	2 (66.7)	3.75 (0.23, N.A.)	7	4 (57.1)	1.45 (0.03, N.A.)	0.908 (0.163, 5.052) 0.9125	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.7536
YES	28	17 (60.7)	5.09 (1.64, 19.55)	26	17 (65.4)	0.76 (0.10, N.A.)	0.543 (0.269, 1.097) 0.0918	
NO	272	173 (63.6)	4.07 (3.12, 6.54)	258	174 (67.4)	0.85 (0.66, 1.41)	0.614 (0.493, 0.765) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	189 (63.2)	N.M.E.	284	191 (67.3)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders

Adverse Events with SOC: Gastrointestinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.8055
POSITIVE	229	146 (63.8)	4.04 (2.73, 6.37)	203	135 (66.5)	0.92 (0.49, 1.41)	0.608 (0.477, 0.776) <0.0001	
NEGATIVE	57	34 (59.6)	6.37 (3.29, 14.19)	76	51 (67.1)	0.85 (0.62, 2.79)	0.611 (0.388, 0.963) 0.0333	
NOT REPORTED	14	10 (71.4)	3.15 (0.07, 19.55)	5	5 (100.0)	0.13 (0.03, 2.37)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	98 (32.7)	21.49 (15.11, N.A.)	284	34 (12.0)	N.A. (N.A., N.A.)	2.228 (1.486, 3.341) <0.0001	
AGE CATEGORIZATION								0.6455
< 65	71	21 (29.6)	N.A. (10.58, N.A.)	87	11 (12.6)	N.A. (N.A., N.A.)	2.059 (0.964, 4.399) 0.0564	
>= 65 AND < 75	151	49 (32.5)	21.49 (16.89, N.A.)	123	11 (8.9)	N.A. (N.A., N.A.)	2.753 (1.396, 5.427) 0.0023	
>= 75	78	28 (35.9)	15.24 (10.09, N.A.)	74	12 (16.2)	N.A. (N.A., N.A.)	1.917 (0.954, 3.850) 0.0627	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5561
MALE	232	70 (30.2)	N.A. (15.11, N.A.)	221	23 (10.4)	N.A. (N.A., N.A.)	2.357 (1.445, 3.845) 0.0004	
FEMALE	68	28 (41.2)	16.89 (6.51, N.A.)	63	11 (17.5)	N.A. (N.A., N.A.)	1.938 (0.938, 4.005) 0.0688	
RACE								0.3494
WHITE	263	86 (32.7)	21.49 (15.11, N.A.)	233	31 (13.3)	N.A. (N.A., N.A.)	1.938 (1.263, 2.972) 0.0020	
ASIAN	26	9 (34.6)	13.27 (5.85, N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	6.355 (1.314, 30.724) 0.0084	
OTHER	11	3 (27.3)	N.A. (1.18, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	4.263 (0.439, 41.399) 0.1741	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.3207
NORTH AMERICA	32	10 (31.3)	17.05 (6.80, N.A.)	25	5 (20.0)	N.A. (6.01, N.A.)	1.107 (0.355, 3.454) 0.8597	
EUROPE	175	56 (32.0)	21.49 (15.11, N.A.)	164	21 (12.8)	N.A. (N.A., N.A.)	1.857 (1.096, 3.145) 0.0194	
ASIA	26	9 (34.6)	13.27 (5.85, N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	6.355 (1.314, 30.724) 0.0084	
REST OF WORLD	67	23 (34.3)	N.A. (9.03, N.A.)	57	6 (10.5)	N.A. (N.A., N.A.)	3.186 (1.276, 7.954) 0.0088	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9354
0	113	39 (34.5)	16.89 (11.70, N.A.)	121	15 (12.4)	N.A. (N.A., N.A.)	2.147 (1.149, 4.011) 0.0142	
>= 1	187	59 (31.6)	22.57 (15.11, N.A.)	163	19 (11.7)	N.A. (N.A., N.A.)	2.269 (1.330, 3.870) 0.0020	
IVRS HISTOLOGY								0.3659
EPITHELIOID	233	75 (32.2)	21.49 (15.11, N.A.)	219	28 (12.8)	N.A. (N.A., N.A.)	1.996 (1.268, 3.142) 0.0023	
NON-EPITHELIOID	67	23 (34.3)	N.A. (9.03, N.A.)	65	6 (9.2)	N.A. (N.A., N.A.)	3.416 (1.364, 8.557) 0.0053	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2879
STAGE I	12	3 (25.0)	N.A. (3.88, N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	5.710 (0.585, 55.750) 0.0918	
STAGE II	23	4 (17.4)	N.A. (11.70, N.A.)	21	4 (19.0)	N.A. (N.A., N.A.)	0.482 (0.088, 2.632) 0.3888	
STAGE III	102	37 (36.3)	21.49 (9.82, N.A.)	101	14 (13.9)	N.A. (N.A., N.A.)	2.063 (1.087, 3.915) 0.0238	
STAGE IV	158	52 (32.9)	16.89 (13.27, N.A.)	140	15 (10.7)	N.A. (N.A., N.A.)	2.506 (1.384, 4.539) 0.0017	
NOT REPORTED	5	2 (40.0)	N.A. (0.07, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.7111
NEVER	124	36 (29.0)	N.A. (10.58, N.A.)	116	13 (11.2)	N.A. (N.A., N.A.)	2.155 (1.117, 4.155) 0.0189	
FORMER	155	54 (34.8)	21.49 (13.27, N.A.)	153	18 (11.8)	N.A. (N.A., N.A.)	2.644 (1.527, 4.581) 0.0003	
CURRENT	18	7 (38.9)	14.19 (9.72, 17.05)	8	1 (12.5)	N.A. (0.62, N.A.)	0.670 (0.059, 7.567) 0.7446	
UNKNOWN	3	1 (33.3)	N.A. (3.75, N.A.)	7	2 (28.6)	N.A. (2.96, N.A.)	0.737 (0.065, 8.322) 0.8043	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2863
YES	28	9 (32.1)	15.11 (7.46, N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	4.284 (0.500, 36.675) 0.1508	
NO	272	89 (32.7)	21.49 (15.24, N.A.)	258	33 (12.8)	N.A. (N.A., N.A.)	2.174 (1.437, 3.288) 0.0002	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	97 (32.4)	N.M.E.	284	34 (12.0)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Diarrhoea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Diarrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.4477
POSITIVE	229	76 (33.2)	21.49 (13.27, N.A.)	203	27 (13.3)	N.A. (N.A., N.A.)	1.973 (1.249, 3.115) 0.0030	
NEGATIVE	57	18 (31.6)	17.61 (14.19, N.A.)	76	7 (9.2)	N.A. (N.A., N.A.)	2.854 (1.138, 7.157) 0.0194	
NOT REPORTED	14	4 (28.6)	N.A. (3.94, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	76 (25.3)	N.A. (N.A., N.A.)	284	124 (43.7)	N.A. (4.53, N.A.)	0.374 (0.276, 0.508) <0.0001	
AGE CATEGORIZATION								0.2405
< 65	71	15 (21.1)	N.A. (17.71, N.A.)	87	45 (51.7)	2.86 (1.05, N.A.)	0.243 (0.128, 0.460) <0.0001	
>= 65 AND < 75	151	41 (27.2)	N.A. (19.55, N.A.)	123	52 (42.3)	N.A. (3.81, N.A.)	0.397 (0.256, 0.617) <0.0001	
>= 75	78	20 (25.6)	N.A. (21.29, N.A.)	74	27 (36.5)	N.A. (N.A., N.A.)	0.529 (0.291, 0.962) 0.0353	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8725
MALE	232	54 (23.3)	N.A. (N.A., N.A.)	221	92 (41.6)	N.A. (N.A., N.A.)	0.346 (0.240, 0.498) <0.0001	
FEMALE	68	22 (32.4)	N.A. (17.71, N.A.)	63	32 (50.8)	3.81 (0.85, N.A.)	0.453 (0.259, 0.792) 0.0047	
RACE								0.3699
WHITE	263	65 (24.7)	N.A. (N.A., N.A.)	233	102 (43.8)	N.A. (4.01, N.A.)	0.372 (0.267, 0.517) <0.0001	
ASIAN	26	9 (34.6)	17.54 (6.37, N.A.)	38	15 (39.5)	N.A. (0.92, N.A.)	0.474 (0.184, 1.225) 0.1181	
OTHER	11	2 (18.2)	N.A. (1.18, N.A.)	13	7 (53.8)	1.48 (0.16, N.A.)	0.256 (0.053, 1.234) 0.0670	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.4642
NORTH AMERICA	32	8 (25.0)	21.29 (21.29, N.A.)	25	13 (52.0)	4.57 (0.30, N.A.)	0.312 (0.124, 0.784) 0.0096	
EUROPE	175	41 (23.4)	N.A. (N.A., N.A.)	164	64 (39.0)	N.A. (N.A., N.A.)	0.386 (0.253, 0.590) <0.0001	
ASIA	26	9 (34.6)	17.54 (6.37, N.A.)	38	15 (39.5)	N.A. (0.92, N.A.)	0.474 (0.184, 1.225) 0.1181	
REST OF WORLD	67	18 (26.9)	N.A. (17.71, N.A.)	57	32 (56.1)	1.48 (0.72, N.A.)	0.323 (0.179, 0.583) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.1178
0	113	37 (32.7)	N.A. (17.71, N.A.)	121	54 (44.6)	N.A. (1.77, N.A.)	0.475 (0.304, 0.741) 0.0009	
>= 1	187	39 (20.9)	N.A. (N.A., N.A.)	163	70 (42.9)	N.A. (3.58, N.A.)	0.314 (0.206, 0.477) <0.0001	
IVRS HISTOLOGY								0.6587
EPITHELIOID	233	55 (23.6)	N.A. (N.A., N.A.)	219	92 (42.0)	N.A. (N.A., N.A.)	0.365 (0.255, 0.521) <0.0001	
NON-EPITHELIOID	67	21 (31.3)	21.29 (12.71, N.A.)	65	32 (49.2)	N.A. (1.22, N.A.)	0.412 (0.228, 0.742) 0.0024	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.5445
STAGE I	12	3 (25.0)	N.A. (1.41, N.A.)	17	5 (29.4)	N.A. (0.82, N.A.)	0.507 (0.098, 2.614) 0.4078	
STAGE II	23	4 (17.4)	N.A. (12.71, N.A.)	21	10 (47.6)	N.A. (0.72, N.A.)	0.208 (0.057, 0.757) 0.0085	
STAGE III	102	34 (33.3)	N.A. (17.54, N.A.)	101	48 (47.5)	N.A. (1.77, N.A.)	0.445 (0.279, 0.709) 0.0005	
STAGE IV	158	34 (21.5)	N.A. (N.A., N.A.)	140	60 (42.9)	N.A. (2.37, N.A.)	0.344 (0.221, 0.536) <0.0001	
NOT REPORTED	5	1 (20.0)	N.A. (9.82, N.A.)	5	1 (20.0)	N.A. (0.85, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.6369
NEVER	124	30 (24.2)	N.A. (19.55, N.A.)	116	54 (46.6)	N.A. (1.38, N.A.)	0.330 (0.205, 0.530) <0.0001	
FORMER	155	43 (27.7)	N.A. (21.29, N.A.)	153	63 (41.2)	N.A. (4.53, N.A.)	0.451 (0.298, 0.681) 0.0001	
CURRENT	18	3 (16.7)	N.A. (14.19, N.A.)	8	3 (37.5)	N.A. (0.03, N.A.)	0.230 (0.038, 1.401) 0.0828	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	4 (57.1)	2.86 (0.03, N.A.)	N.M.E. 0.1323	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.4307
YES	28	5 (17.9)	N.A. (19.55, N.A.)	26	11 (42.3)	N.A. (0.13, N.A.)	0.132 (0.029, 0.595) 0.0020	
NO	272	71 (26.1)	N.A. (N.A., N.A.)	258	113 (43.8)	N.A. (4.01, N.A.)	0.401 (0.293, 0.548) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	76 (25.4)	N.M.E.	284	124 (43.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Nausea

Adverse Events with SOC: Gastrointestinal Disorders and PT: Nausea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.4591
POSITIVE	229	60 (26.2)	N.A. (21.29, N.A.)	203	87 (42.9)	N.A. (4.53, N.A.)	0.411 (0.291, 0.582) <0.0001	
NEGATIVE	57	12 (21.1)	N.A. (14.19, N.A.)	76	33 (43.4)	N.A. (1.22, N.A.)	0.261 (0.123, 0.554) 0.0002	
NOT REPORTED	14	4 (28.6)	N.A. (0.99, N.A.)	5	4 (80.0)	0.76 (0.03, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	57 (19.0)	N.A. (N.A., N.A.)	284	86 (30.3)	N.A. (N.A., N.A.)	0.501 (0.354, 0.711) <0.0001	
AGE CATEGORIZATION								0.1637
< 65	71	14 (19.7)	N.A. (N.A., N.A.)	87	25 (28.7)	N.A. (N.A., N.A.)	0.544 (0.273, 1.083) 0.0789	
>= 65 AND < 75	151	33 (21.9)	N.A. (N.A., N.A.)	123	35 (28.5)	N.A. (N.A., N.A.)	0.610 (0.371, 1.004) 0.0493	
>= 75	78	10 (12.8)	N.A. (N.A., N.A.)	74	26 (35.1)	N.A. (N.A., N.A.)	0.314 (0.151, 0.651) 0.0010	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8707
MALE	232	46 (19.8)	N.A. (N.A., N.A.)	221	70 (31.7)	N.A. (N.A., N.A.)	0.476 (0.322, 0.704) 0.0002	
FEMALE	68	11 (16.2)	N.A. (N.A., N.A.)	63	16 (25.4)	N.A. (N.A., N.A.)	0.617 (0.286, 1.330) 0.2132	
RACE								0.0791
WHITE	263	49 (18.6)	N.A. (N.A., N.A.)	233	58 (24.9)	N.A. (N.A., N.A.)	0.642 (0.434, 0.950) 0.0255	
ASIAN	26	6 (23.1)	N.A. (9.03, N.A.)	38	22 (57.9)	0.39 (0.10, N.A.)	0.254 (0.096, 0.672) 0.0030	
OTHER	11	2 (18.2)	N.A. (1.38, N.A.)	13	6 (46.2)	N.A. (0.76, N.A.)	0.145 (0.017, 1.204) 0.0378	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.2603
NORTH AMERICA	32	8 (25.0)	19.88 (19.88, N.A.)	25	8 (32.0)	N.A. (1.41, N.A.)	0.592 (0.214, 1.637) 0.3159	
EUROPE	175	32 (18.3)	N.A. (N.A., N.A.)	164	43 (26.2)	N.A. (N.A., N.A.)	0.595 (0.372, 0.954) 0.0291	
ASIA	26	6 (23.1)	N.A. (9.03, N.A.)	38	22 (57.9)	0.39 (0.10, N.A.)	0.254 (0.096, 0.672) 0.0030	
REST OF WORLD	67	11 (16.4)	N.A. (N.A., N.A.)	57	13 (22.8)	N.A. (N.A., N.A.)	0.591 (0.253, 1.383) 0.2199	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.6908
0	113	19 (16.8)	N.A. (N.A., N.A.)	121	35 (28.9)	N.A. (N.A., N.A.)	0.436 (0.241, 0.789) 0.0047	
>= 1	187	38 (20.3)	N.A. (N.A., N.A.)	163	51 (31.3)	N.A. (N.A., N.A.)	0.535 (0.347, 0.826) 0.0042	
IVRS HISTOLOGY								0.9188
EPITHELIOID	233	40 (17.2)	N.A. (N.A., N.A.)	219	60 (27.4)	N.A. (N.A., N.A.)	0.479 (0.315, 0.730) 0.0005	
NON-EPITHELIOID	67	17 (25.4)	N.A. (N.A., N.A.)	65	26 (40.0)	N.A. (3.68, N.A.)	0.568 (0.305, 1.059) 0.0702	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7702
STAGE I	12	3 (25.0)	N.A. (1.77, N.A.)	17	6 (35.3)	N.A. (0.13, N.A.)	0.423 (0.085, 2.097) 0.2797	
STAGE II	23	4 (17.4)	N.A. (N.A., N.A.)	21	6 (28.6)	N.A. (2.83, N.A.)	0.583 (0.164, 2.066) 0.3986	
STAGE III	102	23 (22.5)	N.A. (N.A., N.A.)	101	27 (26.7)	N.A. (N.A., N.A.)	0.752 (0.428, 1.321) 0.3232	
STAGE IV	158	27 (17.1)	N.A. (19.88, N.A.)	140	44 (31.4)	N.A. (N.A., N.A.)	0.408 (0.245, 0.681) 0.0004	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	3 (60.0)	1.12 (0.20, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.8930
NEVER	124	21 (16.9)	N.A. (N.A., N.A.)	116	35 (30.2)	N.A. (N.A., N.A.)	0.447 (0.253, 0.790) 0.0044	
FORMER	155	33 (21.3)	N.A. (N.A., N.A.)	153	47 (30.7)	N.A. (N.A., N.A.)	0.557 (0.351, 0.885) 0.0125	
CURRENT	18	3 (16.7)	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.20, N.A.)	0.851 (0.085, 8.514) 0.8908	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	3 (42.9)	4.07 (0.03, N.A.)	N.M.E. 0.1233	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2758
YES	28	7 (25.0)	N.A. (N.A., N.A.)	26	6 (23.1)	N.A. (N.A., N.A.)	1.033 (0.347, 3.076) 0.9532	
NO	272	50 (18.4)	N.A. (N.A., N.A.)	258	80 (31.0)	N.A. (N.A., N.A.)	0.462 (0.319, 0.670) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	56 (18.7)	N.M.E.	284	86 (30.3)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Constipation

Adverse Events with SOC: Gastrointestinal Disorders and PT: Constipation Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9960
POSITIVE	229	47 (20.5)	N.A. (N.A., N.A.)	203	67 (33.0)	N.A. (N.A., N.A.)	0.483 (0.328, 0.713) 0.0002	
NEGATIVE	57	7 (12.3)	N.A. (N.A., N.A.)	76	16 (21.1)	N.A. (N.A., N.A.)	0.488 (0.191, 1.246) 0.1265	
NOT REPORTED	14	3 (21.4)	N.A. (3.32, N.A.)	5	3 (60.0)	2.83 (0.07, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	48 (16.0)	N.A. (N.A., N.A.)	284	55 (19.4)	N.A. (N.A., N.A.)	0.565 (0.370, 0.864) 0.0077	
AGE CATEGORIZATION								0.4196
< 65	71	15 (21.1)	N.A. (16.56, N.A.)	87	27 (31.0)	N.A. (N.A., N.A.)	0.445 (0.221, 0.897) 0.0204	
>= 65 AND < 75	151	26 (17.2)	N.A. (N.A., N.A.)	123	18 (14.6)	N.A. (N.A., N.A.)	0.837 (0.439, 1.595) 0.5929	
>= 75	78	7 (9.0)	N.A. (N.A., N.A.)	74	10 (13.5)	N.A. (N.A., N.A.)	0.443 (0.151, 1.296) 0.1268	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6743
MALE	232	32 (13.8)	N.A. (N.A., N.A.)	221	39 (17.6)	N.A. (N.A., N.A.)	0.474 (0.279, 0.806) 0.0049	
FEMALE	68	16 (23.5)	N.A. (21.52, N.A.)	63	16 (25.4)	N.A. (N.A., N.A.)	0.796 (0.388, 1.631) 0.5372	
RACE								0.2977
WHITE	263	40 (15.2)	N.A. (N.A., N.A.)	233	45 (19.3)	N.A. (N.A., N.A.)	0.533 (0.334, 0.851) 0.0075	
ASIAN	26	7 (26.9)	N.A. (12.45, N.A.)	38	7 (18.4)	N.A. (N.A., N.A.)	1.258 (0.423, 3.744) 0.6794	
OTHER	11	1 (9.1)	N.A. (16.56, N.A.)	13	3 (23.1)	N.A. (0.89, N.A.)	<0.001 (<0.001, N.A.) 0.0918	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5025
NORTH AMERICA	32	4 (12.5)	N.A. (10.64, N.A.)	25	6 (24.0)	N.A. (N.A., N.A.)	0.239 (0.048, 1.187) 0.0585	
EUROPE	175	23 (13.1)	N.A. (N.A., N.A.)	164	25 (15.2)	N.A. (N.A., N.A.)	0.598 (0.323, 1.108) 0.0994	
ASIA	26	7 (26.9)	N.A. (12.45, N.A.)	38	7 (18.4)	N.A. (N.A., N.A.)	1.258 (0.423, 3.744) 0.6794	
REST OF WORLD	67	14 (20.9)	N.A. (16.56, N.A.)	57	17 (29.8)	N.A. (N.A., N.A.)	0.459 (0.210, 1.002) 0.0452	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.1670
0	113	15 (13.3)	N.A. (21.52, N.A.)	121	27 (22.3)	N.A. (N.A., N.A.)	0.402 (0.199, 0.810) 0.0084	
>= 1	187	33 (17.6)	N.A. (N.A., N.A.)	163	28 (17.2)	N.A. (N.A., N.A.)	0.708 (0.410, 1.221) 0.2141	
IVRS HISTOLOGY								0.1248
EPITHELIOID	233	32 (13.7)	N.A. (N.A., N.A.)	219	43 (19.6)	N.A. (N.A., N.A.)	0.466 (0.281, 0.773) 0.0025	
NON-EPITHELIOID	67	16 (23.9)	N.A. (16.56, N.A.)	65	12 (18.5)	N.A. (N.A., N.A.)	0.950 (0.427, 2.115) 0.9025	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.4606
STAGE I	12	1 (8.3)	N.A. (12.52, N.A.)	17	2 (11.8)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.2276	
STAGE II	23	5 (21.7)	N.A. (12.45, N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	1.231 (0.275, 5.504) 0.7855	
STAGE III	102	20 (19.6)	N.A. (21.52, N.A.)	101	19 (18.8)	N.A. (N.A., N.A.)	0.706 (0.354, 1.409) 0.3218	
STAGE IV	158	20 (12.7)	N.A. (N.A., N.A.)	140	30 (21.4)	N.A. (N.A., N.A.)	0.427 (0.233, 0.783) 0.0047	
NOT REPORTED	5	2 (40.0)	9.82 (3.12, 9.82)	5	1 (20.0)	N.A. (2.92, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.8972
NEVER	124	17 (13.7)	N.A. (N.A., N.A.)	116	23 (19.8)	N.A. (N.A., N.A.)	0.496 (0.251, 0.980) 0.0399	
FORMER	155	27 (17.4)	N.A. (21.52, N.A.)	153	29 (19.0)	N.A. (N.A., N.A.)	0.637 (0.360, 1.126) 0.1195	
CURRENT	18	3 (16.7)	N.A. (14.19, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	1 (33.3)	N.A. (0.23, N.A.)	7	3 (42.9)	6.21 (0.07, N.A.)	0.641 (0.066, 6.195) 0.6982	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.4282
YES	28	2 (7.1)	N.A. (N.A., N.A.)	26	4 (15.4)	N.A. (N.A., N.A.)	0.213 (0.024, 1.910) 0.1279	
NO	272	46 (16.9)	N.A. (N.A., N.A.)	258	51 (19.8)	N.A. (N.A., N.A.)	0.596 (0.386, 0.921) 0.0186	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	48 (16.1)	N.M.E.	284	55 (19.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Gastrointestinal Disorders. PT: Vomiting

Adverse Events with SOC: Gastrointestinal Disorders and PT: Vomiting Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.0851
POSITIVE	229	35 (15.3)	N.A. (N.A., N.A.)	203	45 (22.2)	N.A. (N.A., N.A.)	0.449 (0.275, 0.732) 0.0010	
NEGATIVE	57	11 (19.3)	N.A. (14.19, N.A.)	76	10 (13.2)	N.A. (N.A., N.A.)	1.072 (0.423, 2.717) 0.8847	
NOT REPORTED	14	2 (14.3)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	80 (26.7)	N.A. (N.A., N.A.)	284	47 (16.5)	N.A. (N.A., N.A.)	1.446 (0.997, 2.098) 0.0505	
AGE CATEGORIZATION								0.2926
< 65	71	20 (28.2)	N.A. (15.01, N.A.)	87	13 (14.9)	N.A. (N.A., N.A.)	1.698 (0.824, 3.497) 0.1458	
>= 65 AND < 75	151	35 (23.2)	N.A. (N.A., N.A.)	123	23 (18.7)	N.A. (N.A., N.A.)	1.072 (0.620, 1.852) 0.8023	
>= 75	78	25 (32.1)	N.A. (14.09, N.A.)	74	11 (14.9)	N.A. (N.A., N.A.)	2.017 (0.978, 4.162) 0.0529	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8506
MALE	232	63 (27.2)	N.A. (N.A., N.A.)	221	37 (16.7)	N.A. (N.A., N.A.)	1.511 (0.996, 2.293) 0.0504	
FEMALE	68	17 (25.0)	N.A. (N.A., N.A.)	63	10 (15.9)	N.A. (N.A., N.A.)	1.217 (0.533, 2.776) 0.6421	
RACE								0.9551
WHITE	263	76 (28.9)	N.A. (N.A., N.A.)	233	44 (18.9)	N.A. (N.A., N.A.)	1.380 (0.941, 2.023) 0.0979	
ASIAN	26	2 (7.7)	N.A. (N.A., N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	1.517 (0.214, 10.769) 0.6750	
OTHER	11	2 (18.2)	N.A. (6.74, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	1.402 (0.088, 22.410) 0.8105	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5023
NORTH AMERICA	32	7 (21.9)	N.A. (N.A., N.A.)	25	7 (28.0)	N.A. (4.30, N.A.)	0.735 (0.258, 2.099) 0.5639	
EUROPE	175	53 (30.3)	N.A. (18.66, N.A.)	164	28 (17.1)	N.A. (N.A., N.A.)	1.498 (0.931, 2.412) 0.0937	
ASIA	26	2 (7.7)	N.A. (N.A., N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	1.517 (0.214, 10.769) 0.6750	
REST OF WORLD	67	18 (26.9)	N.A. (15.01, N.A.)	57	10 (17.5)	N.A. (N.A., N.A.)	1.520 (0.689, 3.353) 0.2954	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.3859
0	113	29 (25.7)	N.A. (N.A., N.A.)	121	16 (13.2)	N.A. (N.A., N.A.)	1.952 (1.051, 3.623) 0.0308	
>= 1	187	51 (27.3)	N.A. (N.A., N.A.)	163	31 (19.0)	N.A. (N.A., N.A.)	1.195 (0.749, 1.905) 0.4547	
IVRS HISTOLOGY								0.0898
EPITHELIOID	233	66 (28.3)	N.A. (N.A., N.A.)	219	33 (15.1)	N.A. (N.A., N.A.)	1.749 (1.139, 2.685) 0.0097	
NON-EPITHELIOID	67	14 (20.9)	N.A. (15.01, N.A.)	65	14 (21.5)	N.A. (N.A., N.A.)	0.753 (0.342, 1.660) 0.4808	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.5843
STAGE I	12	2 (16.7)	N.A. (2.33, N.A.)	17	3 (17.6)	N.A. (N.A., N.A.)	0.918 (0.153, 5.498) 0.9253	
STAGE II	23	5 (21.7)	N.A. (6.11, N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	1.657 (0.395, 6.939) 0.4852	
STAGE III	102	29 (28.4)	N.A. (N.A., N.A.)	101	12 (11.9)	N.A. (N.A., N.A.)	2.152 (1.076, 4.305) 0.0265	
STAGE IV	158	43 (27.2)	N.A. (15.01, N.A.)	140	28 (20.0)	N.A. (N.A., N.A.)	1.176 (0.717, 1.927) 0.5216	
NOT REPORTED	5	1 (20.0)	N.A. (0.66, N.A.)	5	1 (20.0)	N.A. (3.52, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9696
NEVER	124	34 (27.4)	N.A. (N.A., N.A.)	116	24 (20.7)	N.A. (N.A., N.A.)	1.314 (0.774, 2.232) 0.3116	
FORMER	155	37 (23.9)	N.A. (N.A., N.A.)	153	23 (15.0)	N.A. (N.A., N.A.)	1.319 (0.763, 2.279) 0.3205	
CURRENT	18	9 (50.0)	14.09 (2.53, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.0592	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.8372
YES	28	10 (35.7)	18.66 (7.95, N.A.)	26	6 (23.1)	N.A. (N.A., N.A.)	1.074 (0.361, 3.199) 0.9087	
NO	272	70 (25.7)	N.A. (N.A., N.A.)	258	41 (15.9)	N.A. (N.A., N.A.)	1.501 (1.010, 2.230) 0.0428	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	80 (26.8)	N.M.E.	284	47 (16.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Dyspnoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.1296
POSITIVE	229	62 (27.1)	N.A. (N.A., N.A.)	203	37 (18.2)	N.A. (N.A., N.A.)	1.342 (0.883, 2.039) 0.1670	
NEGATIVE	57	17 (29.8)	N.A. (10.94, N.A.)	76	8 (10.5)	N.A. (N.A., N.A.)	2.417 (1.002, 5.827) 0.0425	
NOT REPORTED	14	1 (7.1)	N.A. (N.A., N.A.)	5	2 (40.0)	6.70 (0.99, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	65 (21.7)	N.A. (N.A., N.A.)	284	25 (8.8)	N.A. (N.A., N.A.)	1.855 (1.141, 3.016) 0.0114	
AGE CATEGORIZATION								0.7268
< 65	71	14 (19.7)	N.A. (14.72, N.A.)	87	9 (10.3)	N.A. (N.A., N.A.)	1.572 (0.651, 3.793) 0.3112	
>= 65 AND < 75	151	40 (26.5)	N.A. (22.28, N.A.)	123	13 (10.6)	N.A. (N.A., N.A.)	1.806 (0.932, 3.501) 0.0757	
>= 75	78	11 (14.1)	N.A. (N.A., N.A.)	74	3 (4.1)	N.A. (N.A., N.A.)	2.706 (0.726, 10.085) 0.1228	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7572
MALE	232	48 (20.7)	N.A. (N.A., N.A.)	221	18 (8.1)	N.A. (N.A., N.A.)	2.035 (1.157, 3.580) 0.0118	
FEMALE	68	17 (25.0)	N.A. (22.28, N.A.)	63	7 (11.1)	N.A. (N.A., N.A.)	1.380 (0.526, 3.619) 0.5109	
RACE								0.9159
WHITE	263	59 (22.4)	N.A. (N.A., N.A.)	233	21 (9.0)	N.A. (N.A., N.A.)	1.903 (1.128, 3.211) 0.0141	
ASIAN	26	4 (15.4)	N.A. (10.09, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.496 (0.302, 7.420) 0.6199	
OTHER	11	2 (18.2)	N.A. (6.74, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	1.248 (0.078, 20.085) 0.8754	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.7892
NORTH AMERICA	32	7 (21.9)	N.A. (9.46, N.A.)	25	4 (16.0)	N.A. (N.A., N.A.)	1.140 (0.322, 4.039) 0.8394	
EUROPE	175	38 (21.7)	N.A. (N.A., N.A.)	164	12 (7.3)	N.A. (N.A., N.A.)	2.094 (1.055, 4.158) 0.0307	
ASIA	26	4 (15.4)	N.A. (10.09, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.496 (0.302, 7.420) 0.6199	
REST OF WORLD	67	16 (23.9)	N.A. (22.28, N.A.)	57	6 (10.5)	N.A. (N.A., N.A.)	1.875 (0.704, 4.999) 0.2010	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.7941
0	113	27 (23.9)	N.A. (N.A., N.A.)	121	11 (9.1)	N.A. (N.A., N.A.)	2.420 (1.179, 4.965) 0.0129	
>= 1	187	38 (20.3)	N.A. (22.28, N.A.)	163	14 (8.6)	N.A. (N.A., N.A.)	1.493 (0.770, 2.895) 0.2323	
IVRS HISTOLOGY								0.3523
EPITHELIOID	233	47 (20.2)	N.A. (N.A., N.A.)	219	20 (9.1)	N.A. (N.A., N.A.)	1.684 (0.969, 2.925) 0.0614	
NON-EPITHELIOID	67	18 (26.9)	N.A. (13.57, N.A.)	65	5 (7.7)	N.A. (N.A., N.A.)	2.581 (0.913, 7.293) 0.0640	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2828
STAGE I	12	3 (25.0)	N.A. (0.95, N.A.)	17	2 (11.8)	N.A. (N.A., N.A.)	2.321 (0.386, 13.951) 0.3436	
STAGE II	23	7 (30.4)	15.05 (8.94, N.A.)	21	2 (9.5)	N.A. (N.A., N.A.)	2.027 (0.371, 11.076) 0.4051	
STAGE III	102	25 (24.5)	N.A. (22.28, N.A.)	101	5 (5.0)	N.A. (N.A., N.A.)	3.586 (1.323, 9.724) 0.0073	
STAGE IV	158	28 (17.7)	N.A. (N.A., N.A.)	140	16 (11.4)	N.A. (N.A., N.A.)	1.204 (0.630, 2.299) 0.5744	
NOT REPORTED	5	2 (40.0)	9.92 (0.10, 9.92)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.8623
NEVER	124	26 (21.0)	N.A. (N.A., N.A.)	116	13 (11.2)	N.A. (N.A., N.A.)	1.582 (0.788, 3.178) 0.1935	
FORMER	155	33 (21.3)	N.A. (22.28, N.A.)	153	11 (7.2)	N.A. (N.A., N.A.)	2.259 (1.106, 4.613) 0.0214	
CURRENT	18	5 (27.8)	14.72 (9.46, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.3178	
UNKNOWN	3	1 (33.3)	N.A. (8.94, N.A.)	7	1 (14.3)	N.A. (3.48, N.A.)	<0.001 (<0.001, N.A.) 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1899
YES	28	5 (17.9)	N.A. (9.30, N.A.)	26	4 (15.4)	N.A. (N.A., N.A.)	0.713 (0.166, 3.054) 0.6467	
NO	272	60 (22.1)	N.A. (N.A., N.A.)	258	21 (8.1)	N.A. (N.A., N.A.)	2.075 (1.231, 3.496) 0.0051	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	65 (21.7)	N.M.E.	284	25 (8.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9851
POSITIVE	229	48 (21.0)	N.A. (N.A., N.A.)	203	17 (8.4)	N.A. (N.A., N.A.)	1.972 (1.108, 3.507) 0.0185	
NEGATIVE	57	12 (21.1)	N.A. (11.63, N.A.)	76	7 (9.2)	N.A. (N.A., N.A.)	1.473 (0.522, 4.158) 0.4633	
NOT REPORTED	14	5 (35.7)	N.A. (2.79, N.A.)	5	1 (20.0)	N.A. (6.70, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	19 (6.3)	N.A. (N.A., N.A.)	284	6 (2.1)	N.A. (N.A., N.A.)	2.602 (1.018, 6.650) 0.0381	
AGE CATEGORIZATION								0.3862
< 65	71	5 (7.0)	N.A. (N.A., N.A.)	87	1 (1.1)	N.A. (N.A., N.A.)	5.096 (0.570, 45.599) 0.1046	
>= 65 AND < 75	151	8 (5.3)	N.A. (N.A., N.A.)	123	4 (3.3)	N.A. (N.A., N.A.)	1.238 (0.349, 4.387) 0.7407	
>= 75	78	6 (7.7)	N.A. (N.A., N.A.)	74	1 (1.4)	N.A. (N.A., N.A.)	5.935 (0.714, 49.317) 0.0609	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6410
MALE	232	17 (7.3)	N.A. (N.A., N.A.)	221	5 (2.3)	N.A. (N.A., N.A.)	2.954 (1.073, 8.130) 0.0278	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	0.930 (0.058, 14.872) 0.9591	
RACE								>0.9999
WHITE	263	19 (7.2)	N.A. (N.A., N.A.)	233	5 (2.1)	N.A. (N.A., N.A.)	2.915 (1.068, 7.958) 0.0286	
ASIAN	26	0	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.4576	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5861
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
EUROPE	175	8 (4.6)	N.A. (N.A., N.A.)	164	4 (2.4)	N.A. (N.A., N.A.)	1.666 (0.488, 5.691) 0.4108	
ASIA	26	0	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.4576	
REST OF WORLD	67	11 (16.4)	N.A. (N.A., N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	8.196 (1.038, 64.723) 0.0172	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.8787
0	113	8 (7.1)	N.A. (N.A., N.A.)	121	3 (2.5)	N.A. (N.A., N.A.)	2.557 (0.661, 9.888) 0.1583	
>= 1	187	11 (5.9)	N.A. (N.A., N.A.)	163	3 (1.8)	N.A. (N.A., N.A.)	2.676 (0.724, 9.892) 0.1245	
IVRS HISTOLOGY								0.9911
EPITHELIOID	233	17 (7.3)	N.A. (N.A., N.A.)	219	6 (2.7)	N.A. (N.A., N.A.)	2.255 (0.866, 5.869) 0.0868	
NON-EPITHELIOID	67	2 (3.0)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.1540	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7985
STAGE I	12	1 (8.3)	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. 0.2138	
STAGE II	23	0	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE III	102	7 (6.9)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	6.072 (0.731, 50.415) 0.0566	
STAGE IV	158	11 (7.0)	N.A. (N.A., N.A.)	140	5 (3.6)	N.A. (N.A., N.A.)	1.644 (0.551, 4.908) 0.3681	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9671
NEVER	124	7 (5.6)	N.A. (N.A., N.A.)	116	3 (2.6)	N.A. (N.A., N.A.)	2.281 (0.590, 8.822) 0.2188	
FORMER	155	11 (7.1)	N.A. (N.A., N.A.)	153	3 (2.0)	N.A. (N.A., N.A.)	3.086 (0.835, 11.403) 0.0750	
CURRENT	18	1 (5.6)	N.A. (13.04, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.3741
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	0.925 (0.058, 14.794) 0.9560	
NO	272	18 (6.6)	N.A. (N.A., N.A.)	258	5 (1.9)	N.A. (N.A., N.A.)	2.945 (1.070, 8.105) 0.0282	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	19 (6.4)	N.M.E.	284	6 (2.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pleural Effusion

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pleural Effusion Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.7762
POSITIVE	229	13 (5.7)	N.A. (N.A., N.A.)	203	4 (2.0)	N.A. (N.A., N.A.)	2.500 (0.796, 7.852) 0.1045	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	2.749 (0.249, 30.321) 0.3892	
NOT REPORTED	14	3 (21.4)	N.A. (1.45, N.A.)	5	1 (20.0)	N.A. (6.77, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	18 (6.0)	N.A. (N.A., N.A.)	284	1 (0.4)	N.A. (N.A., N.A.)	13.188 (1.732, 100.414) 0.0012	
AGE CATEGORIZATION								N.M.E.
< 65	71	4 (5.6)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	7 (4.6)	N.M.E.	123	1 (0.8)	N.M.E.	N.M.E.	
>= 75	78	7 (9.0)	N.M.E.	74	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9906
MALE	232	15 (6.5)	N.A. (N.A., N.A.)	221	1 (0.5)	N.A. (N.A., N.A.)	10.830 (1.398, 83.890) 0.0042	
FEMALE	68	3 (4.4)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.1213	
RACE								>0.9999
WHITE	263	16 (6.1)	N.A. (N.A., N.A.)	233	1 (0.4)	N.A. (N.A., N.A.)	12.327 (1.619, 93.868) 0.0019	
ASIAN	26	2 (7.7)	N.A. (11.79, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	1 (3.1)	N.A. (20.76, N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.2557	
EUROPE	175	10 (5.7)	N.A. (N.A., N.A.)	164	0	N.A. (N.A., N.A.)	N.M.E. 0.0045	
ASIA	26	2 (7.7)	N.A. (11.79, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
REST OF WORLD	67	5 (7.5)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.0313	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
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by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9914
0	113	5 (4.4)	N.A. (N.A., N.A.)	121	0	N.A. (N.A., N.A.)	N.M.E. 0.0715	
>= 1	187	13 (7.0)	N.A. (N.A., N.A.)	163	1 (0.6)	N.A. (N.A., N.A.)	9.466 (1.219, 73.506) 0.0086	
IVRS HISTOLOGY								0.9918
EPITHELIOID	233	17 (7.3)	N.A. (N.A., N.A.)	219	1 (0.5)	N.A. (N.A., N.A.)	13.129 (1.724, 99.969) 0.0013	
NON-EPITHELIOID	67	1 (1.5)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	2 (8.7)	N.A. (11.79, N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.3393	
STAGE III	102	11 (10.8)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	9.904 (1.265, 77.560) 0.0072	
STAGE IV	158	5 (3.2)	N.A. (N.A., N.A.)	140	0	N.A. (N.A., N.A.)	N.M.E. 0.1027	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	2 (1.6)	N.A. (N.A., N.A.)	116	0	N.A. (N.A., N.A.)	N.M.E. 0.2512	
FORMER	155	14 (9.0)	N.A. (N.A., N.A.)	153	1 (0.7)	N.A. (N.A., N.A.)	11.426 (1.475, 88.512) 0.0032	
CURRENT	18	2 (11.1)	N.A. (20.76, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9914
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.3447	
NO	272	17 (6.3)	N.A. (N.A., N.A.)	258	1 (0.4)	N.A. (N.A., N.A.)	12.335 (1.611, 94.430) 0.0019	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	18 (6.0)	N.M.E.	284	1 (0.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Pneumonitis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9935
POSITIVE	229	14 (6.1)	N.A. (N.A., N.A.)	203	1 (0.5)	N.A. (N.A., N.A.)	8.619 (1.100, 67.532) 0.0137	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.0994	
NOT REPORTED	14	2 (14.3)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	13 (4.3)	N.A. (N.A., N.A.)	284	3 (1.1)	N.A. (N.A., N.A.)	4.314 (1.229, 15.141) 0.0128	
AGE CATEGORIZATION								N.M.E.
< 65	71	5 (7.0)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	3 (2.0)	N.M.E.	123	3 (2.4)	N.M.E.	N.M.E.	
>= 75	78	5 (6.4)	N.M.E.	74	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9926
MALE	232	11 (4.7)	N.A. (N.A., N.A.)	221	3 (1.4)	N.A. (N.A., N.A.)	3.690 (1.029, 13.228) 0.0316	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.1619	
RACE								0.6617
WHITE	263	12 (4.6)	N.A. (N.A., N.A.)	233	2 (0.9)	N.A. (N.A., N.A.)	5.492 (1.230, 24.534) 0.0121	
ASIAN	26	0	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	11	1 (9.1)	N.A. (4.93, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	1.588 (0.099, 25.566) 0.7422	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	2 (6.3)	N.M.E.	25	1 (4.0)	N.M.E.	N.M.E.	
EUROPE	175	6 (3.4)	N.M.E.	164	1 (0.6)	N.M.E.	N.M.E.	
ASIA	26	0	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	5 (7.5)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9570
0	113	4 (3.5)	N.A. (N.A., N.A.)	121	1 (0.8)	N.A. (N.A., N.A.)	4.415 (0.493, 39.506) 0.1461	
>= 1	187	9 (4.8)	N.A. (N.A., N.A.)	163	2 (1.2)	N.A. (N.A., N.A.)	4.042 (0.873, 18.708) 0.0529	
IVRS HISTOLOGY								0.8686
EPITHELIOID	233	8 (3.4)	N.A. (N.A., N.A.)	219	2 (0.9)	N.A. (N.A., N.A.)	3.956 (0.840, 18.635) 0.0602	
NON-EPITHELIOID	67	5 (7.5)	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	4.939 (0.577, 42.304) 0.1058	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	1 (8.3)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	2 (8.7)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	6 (5.9)	N.M.E.	101	1 (1.0)	N.M.E.	N.M.E.	
STAGE IV	158	4 (2.5)	N.M.E.	140	1 (0.7)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.7799
NEVER	124	1 (0.8)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	1.025 (0.064, 16.414) 0.9861	
FORMER	155	10 (6.5)	N.A. (N.A., N.A.)	153	2 (1.3)	N.A. (N.A., N.A.)	5.269 (1.154, 24.052) 0.0164	
CURRENT	18	2 (11.1)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.3388	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9994
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	13 (4.8)	N.A. (N.A., N.A.)	258	3 (1.2)	N.A. (N.A., N.A.)	4.351 (1.239, 15.270) 0.0122	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	13 (4.3)	N.M.E.	284	3 (1.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Productive Cough

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Productive Cough Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9922
POSITIVE	229	11 (4.8)	N.A. (N.A., N.A.)	203	3 (1.5)	N.A. (N.A., N.A.)	3.350 (0.934, 12.012) 0.0487	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.2272	
NOT REPORTED	14	1 (7.1)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	7 (2.3)	N.A. (N.A., N.A.)	284	14 (4.9)	N.A. (N.A., N.A.)	0.334 (0.120, 0.927) 0.0270	
AGE CATEGORIZATION								0.9514
< 65	71	1 (1.4)	N.A. (N.A., N.A.)	87	3 (3.4)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.1168	
>= 65 AND < 75	151	4 (2.6)	N.A. (N.A., N.A.)	123	6 (4.9)	N.A. (N.A., N.A.)	0.413 (0.103, 1.651) 0.1963	
>= 75	78	2 (2.6)	N.A. (N.A., N.A.)	74	5 (6.8)	N.A. (N.A., N.A.)	0.366 (0.071, 1.885) 0.2095	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9897
MALE	232	7 (3.0)	N.A. (N.A., N.A.)	221	11 (5.0)	N.A. (N.A., N.A.)	0.430 (0.150, 1.239) 0.1073	
FEMALE	68	0	N.A. (N.A., N.A.)	63	3 (4.8)	N.A. (N.A., N.A.)	N.M.E. 0.0675	
RACE								>0.9999
WHITE	263	7 (2.7)	N.A. (N.A., N.A.)	233	10 (4.3)	N.A. (N.A., N.A.)	0.441 (0.151, 1.289) 0.1238	
ASIAN	26	0	N.A. (N.A., N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	N.M.E. 0.0909	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.7573
NORTH AMERICA	32	1 (3.1)	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.3768	
EUROPE	175	4 (2.3)	N.A. (N.A., N.A.)	164	9 (5.5)	N.A. (N.A., N.A.)	0.201 (0.043, 0.930) 0.0227	
ASIA	26	0	N.A. (N.A., N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	N.M.E. 0.0909	
REST OF WORLD	67	2 (3.0)	N.A. (N.A., N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	1.788 (0.162, 19.726) 0.6302	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.3724
0	113	3 (2.7)	N.A. (N.A., N.A.)	121	4 (3.3)	N.A. (N.A., N.A.)	0.542 (0.099, 2.958) 0.4721	
>= 1	187	4 (2.1)	N.A. (N.A., N.A.)	163	10 (6.1)	N.A. (N.A., N.A.)	0.255 (0.070, 0.925) 0.0248	
IVRS HISTOLOGY								0.4937
EPITHELIOID	233	6 (2.6)	N.A. (N.A., N.A.)	219	10 (4.6)	N.A. (N.A., N.A.)	0.373 (0.117, 1.189) 0.0828	
NON-EPITHELIOID	67	1 (1.5)	N.A. (N.A., N.A.)	65	4 (6.2)	N.A. (N.A., N.A.)	0.243 (0.027, 2.175) 0.1697	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9265
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	2 (9.5)	N.A. (N.A., N.A.)	0.484 (0.044, 5.347) 0.5454	
STAGE III	102	0	N.A. (N.A., N.A.)	101	7 (6.9)	N.A. (N.A., N.A.)	N.M.E. 0.0070	
STAGE IV	158	6 (3.8)	N.A. (N.A., N.A.)	140	5 (3.6)	N.A. (N.A., N.A.)	0.707 (0.190, 2.633) 0.6037	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9751
NEVER	124	2 (1.6)	N.A. (N.A., N.A.)	116	6 (5.2)	N.A. (N.A., N.A.)	0.308 (0.062, 1.527) 0.1273	
FORMER	155	4 (2.6)	N.A. (N.A., N.A.)	153	8 (5.2)	N.A. (N.A., N.A.)	0.245 (0.052, 1.154) 0.0537	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9997
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	7 (2.6)	N.A. (N.A., N.A.)	258	14 (5.4)	N.A. (N.A., N.A.)	0.336 (0.121, 0.932) 0.0278	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	7 (2.3)	N.M.E.	284	14 (4.9)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Epistaxis Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9577
POSITIVE	229	6 (2.6)	N.A. (N.A., N.A.)	203	11 (5.4)	N.A. (N.A., N.A.)	0.316 (0.100, 0.991) 0.0369	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	3 (3.9)	N.A. (N.A., N.A.)	0.454 (0.047, 4.367) 0.4831	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	2 (0.7)	N.A. (N.A., N.A.)	284	17 (6.0)	N.A. (N.A., N.A.)	0.108 (0.025, 0.468) 0.0003	
AGE CATEGORIZATION								0.8175
< 65	71	0	N.A. (N.A., N.A.)	87	4 (4.6)	N.A. (N.A., N.A.)	N.M.E. 0.0679	
>= 65 AND < 75	151	1 (0.7)	N.A. (N.A., N.A.)	123	9 (7.3)	N.A. (N.A., N.A.)	0.088 (0.011, 0.695) 0.0036	
>= 75	78	1 (1.3)	N.A. (N.A., N.A.)	74	4 (5.4)	N.A. (N.A., N.A.)	0.232 (0.026, 2.073) 0.1534	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9993
MALE	232	2 (0.9)	N.A. (N.A., N.A.)	221	17 (7.7)	N.A. (N.A., N.A.)	0.108 (0.025, 0.467) 0.0003	
FEMALE	68	0	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
RACE								0.9864
WHITE	263	1 (0.4)	N.A. (N.A., N.A.)	233	6 (2.6)	N.A. (N.A., N.A.)	0.147 (0.018, 1.218) 0.0391	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	11 (28.9)	N.A. (N.A., N.A.)	0.115 (0.015, 0.889) 0.0125	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9919
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
EUROPE	175	1 (0.6)	N.A. (N.A., N.A.)	164	5 (3.0)	N.A. (N.A., N.A.)	0.184 (0.022, 1.576) 0.0826	
ASIA	26	1 (3.8)	N.A. (N.A., N.A.)	38	11 (28.9)	N.A. (N.A., N.A.)	0.115 (0.015, 0.889) 0.0125	
REST OF WORLD	67	0	N.A. (N.A., N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	N.M.E. 0.3047	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9902
0	113	0	N.A. (N.A., N.A.)	121	6 (5.0)	N.A. (N.A., N.A.)	N.M.E. 0.0161	
>= 1	187	2 (1.1)	N.A. (N.A., N.A.)	163	11 (6.7)	N.A. (N.A., N.A.)	0.154 (0.034, 0.697) 0.0051	
IVRS HISTOLOGY								0.9887
EPITHELIOID	233	0	N.A. (N.A., N.A.)	219	10 (4.6)	N.A. (N.A., N.A.)	N.M.E. 0.0009	
NON-EPITHELIOID	67	2 (3.0)	N.A. (N.A., N.A.)	65	7 (10.8)	N.A. (N.A., N.A.)	0.269 (0.056, 1.296) 0.0801	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.5515
STAGE I	12	0	N.A. (N.A., N.A.)	17	2 (11.8)	N.A. (N.A., N.A.)	N.M.E. 0.2276	
STAGE II	23	0	N.A. (N.A., N.A.)	21	2 (9.5)	N.A. (N.A., N.A.)	N.M.E. 0.1341	
STAGE III	102	1 (1.0)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	0.980 (0.061, 15.674) 0.9888	
STAGE IV	158	1 (0.6)	N.A. (N.A., N.A.)	140	11 (7.9)	N.A. (N.A., N.A.)	0.078 (0.010, 0.602) 0.0016	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (0.76, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	0	N.A. (N.A., N.A.)	116	3 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.0708	
FORMER	155	2 (1.3)	N.A. (N.A., N.A.)	153	13 (8.5)	N.A. (N.A., N.A.)	0.147 (0.033, 0.651) 0.0034	
CURRENT	18	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.10, N.A.)	N.M.E. 0.1336	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9991
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	2 (0.7)	N.A. (N.A., N.A.)	258	17 (6.6)	N.A. (N.A., N.A.)	0.108 (0.025, 0.469) 0.0003	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	2 (0.7)	N.M.E.	284	17 (6.0)	N.M.E.	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Hiccups

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Hiccups Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9937
POSITIVE	229	2 (0.9)	N.A. (N.A., N.A.)	203	15 (7.4)	N.A. (N.A., N.A.)	0.113 (0.026, 0.496) 0.0005	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	2 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.2191	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
OVERALL	300	2 (0.7)	N.A. (N.A., N.A.)	284	12 (4.2)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0004	
AGE CATEGORIZATION								N.M.E.
< 65	71	0	N.M.E.	87	4 (4.6)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	1 (0.7)	N.M.E.	123	4 (3.3)	N.M.E.	N.M.E.	
>= 75	78	1 (1.3)	N.M.E.	74	4 (5.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	232	1 (0.4)	N.M.E.	221	8 (3.6)	N.M.E.	N.M.E.	
FEMALE	68	1 (1.5)	N.M.E.	63	4 (6.3)	N.M.E.	N.M.E.	
RACE								>0.9999
WHITE	263	1 (0.4)	N.A. (N.A., N.A.)	233	11 (4.7)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0004	
ASIAN	26	1 (3.8)	N.A. (11.10, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	11	0	N.A. (N.A., N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	N.M.E. 0.3613	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	N.M.E. 0.2352	
EUROPE	175	1 (0.6)	N.A. (N.A., N.A.)	164	9 (5.5)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0017	
ASIA	26	1 (3.8)	N.A. (11.10, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
REST OF WORLD	67	0	N.A. (N.A., N.A.)	57	2 (3.5)	N.A. (N.A., N.A.)	N.M.E. 0.1413	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	1 (0.9)	N.M.E.	121	6 (5.0)	N.M.E.	N.M.E.	
>= 1	187	1 (0.5)	N.M.E.	163	6 (3.7)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								0.9948
EPITHELIOID	233	2 (0.9)	N.A. (N.A., N.A.)	219	10 (4.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0011	
NON-EPITHELIOID	67	0	N.A. (N.A., N.A.)	65	2 (3.1)	N.A. (N.A., N.A.)	N.M.E. 0.1542	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	0	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	0	N.M.E.	21	1 (4.8)	N.M.E.	N.M.E.	
STAGE III	102	1 (1.0)	N.M.E.	101	8 (7.9)	N.M.E.	N.M.E.	
STAGE IV	158	1 (0.6)	N.M.E.	140	3 (2.1)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	1 (0.8)	N.M.E.	116	8 (6.9)	N.M.E.	N.M.E.	
FORMER	155	1 (0.6)	N.M.E.	153	4 (2.6)	N.M.E.	N.M.E.	
CURRENT	18	0	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9965
YES	28	0	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	N.M.E. 0.2971	
NO	272	2 (0.7)	N.A. (N.A., N.A.)	258	11 (4.3)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0006	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	2 (0.7)	N.M.E.	284	12 (4.2)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Rhinorrhoea

Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders and PT: Rhinorrhoea Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9950
POSITIVE	229	2 (0.9)	N.A. (N.A., N.A.)	203	9 (4.4)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0013	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	3 (3.9)	N.A. (N.A., N.A.)	N.M.E. 0.1368	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	155 (51.7)	6.60 (4.63, 10.84)	284	67 (23.6)	N.A. (N.A., N.A.)	2.207 (1.649, 2.954) <0.0001	
AGE CATEGORIZATION								0.6243
< 65	71	28 (39.4)	22.01 (5.75, N.A.)	87	18 (20.7)	N.A. (N.A., N.A.)	1.853 (1.011, 3.400) 0.0431	
>= 65 AND < 75	151	82 (54.3)	5.59 (3.25, 11.99)	123	26 (21.1)	N.A. (N.A., N.A.)	2.619 (1.674, 4.096) <0.0001	
>= 75	78	45 (57.7)	5.13 (2.73, 7.62)	74	23 (31.1)	N.A. (N.A., N.A.)	1.863 (1.117, 3.109) 0.0153	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0001**
MALE	232	124 (53.4)	5.13 (3.29, 9.20)	221	42 (19.0)	N.A. (N.A., N.A.)	3.157 (2.215, 4.500) <0.0001	
FEMALE	68	31 (45.6)	10.84 (7.03, N.A.)	63	25 (39.7)	N.A. (2.79, N.A.)	0.779 (0.446, 1.362) 0.3825	
RACE								0.1934
WHITE	263	134 (51.0)	7.16 (4.73, 11.10)	233	58 (24.9)	N.A. (N.A., N.A.)	1.976 (1.444, 2.704) <0.0001	
ASIAN	26	17 (65.4)	1.71 (0.43, 6.60)	38	8 (21.1)	N.A. (N.A., N.A.)	4.651 (1.949, 11.099) 0.0002	
OTHER	11	4 (36.4)	N.A. (1.48, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	5.057 (0.563, 45.426) 0.1078	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.0418**
NORTH AMERICA	32	18 (56.3)	4.63 (1.18, 11.10)	25	9 (36.0)	N.A. (1.35, N.A.)	1.403 (0.619, 3.180) 0.4103	
EUROPE	175	84 (48.0)	9.20 (5.49, 22.01)	164	42 (25.6)	N.A. (N.A., N.A.)	1.688 (1.156, 2.465) 0.0061	
ASIA	26	17 (65.4)	1.71 (0.43, 6.60)	38	8 (21.1)	N.A. (N.A., N.A.)	4.651 (1.949, 11.099) 0.0002	
REST OF WORLD	67	36 (53.7)	4.50 (1.84, N.A.)	57	8 (14.0)	N.A. (N.A., N.A.)	4.585 (2.118, 9.924) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.5442
0	113	61 (54.0)	6.05 (3.52, 22.01)	121	27 (22.3)	N.A. (N.A., N.A.)	2.476 (1.564, 3.920) <0.0001	
>= 1	187	94 (50.3)	7.36 (3.71, 11.99)	163	40 (24.5)	N.A. (N.A., N.A.)	2.037 (1.397, 2.971) 0.0002	
IVRS HISTOLOGY								0.0875
EPITHELIOID	233	117 (50.2)	7.03 (4.86, 11.99)	219	55 (25.1)	N.A. (N.A., N.A.)	1.962 (1.417, 2.717) <0.0001	
NON-EPITHELIOID	67	38 (56.7)	4.63 (2.00, 11.40)	65	12 (18.5)	N.A. (N.A., N.A.)	3.414 (1.758, 6.632) 0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7205
STAGE I	12	6 (50.0)	4.63 (0.82, N.A.)	17	5 (29.4)	N.A. (0.72, N.A.)	1.824 (0.552, 6.027) 0.3165	
STAGE II	23	17 (73.9)	1.38 (0.53, 5.13)	21	6 (28.6)	N.A. (3.52, N.A.)	3.366 (1.301, 8.710) 0.0083	
STAGE III	102	60 (58.8)	5.59 (2.79, 10.84)	101	26 (25.7)	N.A. (N.A., N.A.)	2.086 (1.300, 3.350) 0.0018	
STAGE IV	158	68 (43.0)	22.01 (5.75, N.A.)	140	29 (20.7)	N.A. (N.A., N.A.)	2.128 (1.370, 3.303) 0.0006	
NOT REPORTED	5	4 (80.0)	0.72 (0.07, N.A.)	5	1 (20.0)	N.A. (0.49, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.3342
NEVER	124	56 (45.2)	11.99 (5.75, 23.85)	116	29 (25.0)	N.A. (N.A., N.A.)	1.547 (0.974, 2.456) 0.0615	
FORMER	155	88 (56.8)	4.63 (3.02, 7.16)	153	34 (22.2)	N.A. (N.A., N.A.)	2.903 (1.943, 4.337) <0.0001	
CURRENT	18	8 (44.4)	N.A. (1.64, N.A.)	8	1 (12.5)	N.A. (1.58, N.A.)	4.123 (0.515, 32.986) 0.1473	
UNKNOWN	3	3 (100.0)	0.30 (0.07, 6.05)	7	3 (42.9)	N.A. (0.03, N.A.)	2.592 (0.510, 13.189) 0.2402	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.6938
YES	28	13 (46.4)	6.05 (2.79, N.A.)	26	6 (23.1)	N.A. (N.A., N.A.)	2.084 (0.790, 5.498) 0.1261	
NO	272	142 (52.2)	6.60 (4.24, 10.84)	258	61 (23.6)	N.A. (N.A., N.A.)	2.220 (1.635, 3.014) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	155 (51.8)	N.M.E.	284	67 (23.6)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.0693
POSITIVE	229	126 (55.0)	5.13 (3.35, 8.74)	203	45 (22.2)	N.A. (N.A., N.A.)	2.606 (1.844, 3.683) <0.0001	
NEGATIVE	57	23 (40.4)	23.85 (4.63, N.A.)	76	21 (27.6)	N.A. (N.A., N.A.)	1.371 (0.751, 2.503) 0.2984	
NOT REPORTED	14	6 (42.9)	N.A. (3.35, N.A.)	5	1 (20.0)	N.A. (0.13, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	62 (20.7)	N.A. (N.A., N.A.)	284	5 (1.8)	N.A. (N.A., N.A.)	10.238 (4.080, 25.691) <0.0001	
AGE CATEGORIZATION								0.2300
< 65	71	11 (15.5)	N.A. (22.01, N.A.)	87	3 (3.4)	N.A. (N.A., N.A.)	3.969 (1.074, 14.671) 0.0255	
>= 65 AND < 75	151	27 (17.9)	N.A. (N.A., N.A.)	123	1 (0.8)	N.A. (N.A., N.A.)	19.879 (2.680, 147.460) <0.0001	
>= 75	78	24 (30.8)	17.31 (10.38, N.A.)	74	1 (1.4)	N.A. (N.A., N.A.)	18.937 (2.529, 141.819) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9873
MALE	232	49 (21.1)	N.A. (N.A., N.A.)	221	5 (2.3)	N.A. (N.A., N.A.)	8.461 (3.339, 21.439) <0.0001	
FEMALE	68	13 (19.1)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0030	
RACE								0.9998
WHITE	263	56 (21.3)	N.A. (N.A., N.A.)	233	5 (2.1)	N.A. (N.A., N.A.)	8.796 (3.492, 22.155) <0.0001	
ASIAN	26	4 (15.4)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0101	
OTHER	11	2 (18.2)	N.A. (16.07, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	8 (25.0)	N.A. (11.10, N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.0131	
EUROPE	175	40 (22.9)	N.A. (22.01, N.A.)	164	5 (3.0)	N.A. (N.A., N.A.)	6.099 (2.369, 15.701) <0.0001	
ASIA	26	4 (15.4)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0101	
REST OF WORLD	67	10 (14.9)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.0053	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9787
0	113	21 (18.6)	N.A. (N.A., N.A.)	121	5 (4.1)	N.A. (N.A., N.A.)	4.114 (1.527, 11.085) 0.0024	
>= 1	187	41 (21.9)	N.A. (N.A., N.A.)	163	0	N.A. (N.A., N.A.)	N.M.E. <0.0001	
IVRS HISTOLOGY								0.9039
EPITHELIOID	233	51 (21.9)	N.A. (N.A., N.A.)	219	4 (1.8)	N.A. (N.A., N.A.)	10.451 (3.740, 29.204) <0.0001	
NON-EPITHELIOID	67	11 (16.4)	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	9.395 (1.190, 74.170) 0.0094	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.4785
STAGE I	12	2 (16.7)	N.A. (4.63, N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	3.059 (0.276, 33.943) 0.3380	
STAGE II	23	4 (17.4)	N.A. (N.A., N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	4.019 (0.449, 35.987) 0.1783	
STAGE III	102	25 (24.5)	N.A. (17.31, N.A.)	101	2 (2.0)	N.A. (N.A., N.A.)	7.598 (1.732, 33.322) 0.0016	
STAGE IV	158	27 (17.1)	N.A. (N.A., N.A.)	140	1 (0.7)	N.A. (N.A., N.A.)	24.373 (3.302, 179.909) <0.0001	
NOT REPORTED	5	4 (80.0)	0.72 (0.07, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.5629
NEVER	124	22 (17.7)	N.A. (N.A., N.A.)	116	2 (1.7)	N.A. (N.A., N.A.)	9.047 (2.099, 39.002) 0.0003	
FORMER	155	38 (24.5)	N.A. (N.A., N.A.)	153	2 (1.3)	N.A. (N.A., N.A.)	16.343 (3.901, 68.459) <0.0001	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	1 (33.3)	N.A. (0.07, N.A.)	7	1 (14.3)	N.A. (6.28, N.A.)	2.160 (0.135, 34.605) 0.5770	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.5536
YES	28	7 (25.0)	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	6.684 (0.822, 54.356) 0.0399	
NO	272	55 (20.2)	N.A. (N.A., N.A.)	258	4 (1.6)	N.A. (N.A., N.A.)	11.024 (3.954, 30.737) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	62 (20.7)	N.M.E.	284	5 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Pruritus Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.6683
POSITIVE	229	47 (20.5)	N.A. (N.A., N.A.)	203	4 (2.0)	N.A. (N.A., N.A.)	9.092 (3.245, 25.472) <0.0001	
NEGATIVE	57	12 (21.1)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	13.874 (1.763, 109.165) 0.0011	
NOT REPORTED	14	3 (21.4)	N.A. (10.38, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	60 (20.0)	N.A. (N.A., N.A.)	284	21 (7.4)	N.A. (N.A., N.A.)	2.274 (1.365, 3.790) 0.0012	
AGE CATEGORIZATION								0.1938
< 65	71	16 (22.5)	N.A. (22.34, N.A.)	87	4 (4.6)	N.A. (N.A., N.A.)	4.161 (1.356, 12.768) 0.0068	
>= 65 AND < 75	151	32 (21.2)	N.A. (N.A., N.A.)	123	9 (7.3)	N.A. (N.A., N.A.)	2.342 (1.095, 5.010) 0.0239	
>= 75	78	12 (15.4)	N.A. (N.A., N.A.)	74	8 (10.8)	N.A. (N.A., N.A.)	1.294 (0.520, 3.219) 0.5791	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0180**
MALE	232	50 (21.6)	N.A. (N.A., N.A.)	221	13 (5.9)	N.A. (N.A., N.A.)	3.331 (1.791, 6.196) <0.0001	
FEMALE	68	10 (14.7)	N.A. (N.A., N.A.)	63	8 (12.7)	N.A. (N.A., N.A.)	0.672 (0.238, 1.893) 0.4491	
RACE								0.1970
WHITE	263	46 (17.5)	N.A. (N.A., N.A.)	233	19 (8.2)	N.A. (N.A., N.A.)	1.848 (1.069, 3.195) 0.0254	
ASIAN	26	11 (42.3)	17.38 (1.71, N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	5.685 (1.179, 27.419) 0.0147	
OTHER	11	3 (27.3)	N.A. (1.48, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.0482	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.2332
NORTH AMERICA	32	3 (9.4)	N.A. (N.A., N.A.)	25	2 (8.0)	N.A. (N.A., N.A.)	1.098 (0.183, 6.576) 0.9181	
EUROPE	175	33 (18.9)	N.A. (N.A., N.A.)	164	14 (8.5)	N.A. (N.A., N.A.)	1.877 (0.988, 3.566) 0.0505	
ASIA	26	11 (42.3)	17.38 (1.71, N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	5.685 (1.179, 27.419) 0.0147	
REST OF WORLD	67	13 (19.4)	N.A. (N.A., N.A.)	57	3 (5.3)	N.A. (N.A., N.A.)	3.368 (0.942, 12.035) 0.0472	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.7746
0	113	25 (22.1)	N.A. (22.34, N.A.)	121	9 (7.4)	N.A. (N.A., N.A.)	2.308 (1.047, 5.086) 0.0324	
>= 1	187	35 (18.7)	N.A. (N.A., N.A.)	163	12 (7.4)	N.A. (N.A., N.A.)	2.259 (1.156, 4.414) 0.0143	
IVRS HISTOLOGY								0.2881
EPITHELIOID	233	43 (18.5)	N.A. (N.A., N.A.)	219	17 (7.8)	N.A. (N.A., N.A.)	2.091 (1.178, 3.710) 0.0099	
NON-EPITHELIOID	67	17 (25.4)	17.51 (12.62, N.A.)	65	4 (6.2)	N.A. (N.A., N.A.)	3.091 (0.997, 9.587) 0.0394	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.2828
STAGE I	12	2 (16.7)	N.A. (3.45, N.A.)	17	3 (17.6)	N.A. (N.A., N.A.)	0.966 (0.161, 5.798) 0.9696	
STAGE II	23	6 (26.1)	N.A. (11.40, N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	3.713 (0.415, 33.237) 0.2093	
STAGE III	102	18 (17.6)	N.A. (N.A., N.A.)	101	9 (8.9)	N.A. (N.A., N.A.)	1.346 (0.571, 3.172) 0.4951	
STAGE IV	158	32 (20.3)	N.A. (N.A., N.A.)	140	7 (5.0)	N.A. (N.A., N.A.)	3.875 (1.697, 8.849) 0.0005	
NOT REPORTED	5	2 (40.0)	N.A. (0.72, N.A.)	5	1 (20.0)	N.A. (0.49, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.8617
NEVER	124	19 (15.3)	N.A. (N.A., N.A.)	116	9 (7.8)	N.A. (N.A., N.A.)	1.553 (0.679, 3.548) 0.2931	
FORMER	155	36 (23.2)	N.A. (N.A., N.A.)	153	12 (7.8)	N.A. (N.A., N.A.)	2.507 (1.281, 4.907) 0.0055	
CURRENT	18	4 (22.2)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.1629	
UNKNOWN	3	1 (33.3)	N.A. (6.05, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.2482	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9845
YES	28	2 (7.1)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.1664	
NO	272	58 (21.3)	N.A. (N.A., N.A.)	258	21 (8.1)	N.A. (N.A., N.A.)	2.194 (1.312, 3.668) 0.0021	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	60 (20.1)	N.M.E.	284	21 (7.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Rash Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.0272**
POSITIVE	229	51 (22.3)	N.A. (N.A., N.A.)	203	11 (5.4)	N.A. (N.A., N.A.)	3.471 (1.785, 6.751) <0.0001	
NEGATIVE	57	8 (14.0)	N.A. (N.A., N.A.)	76	9 (11.8)	N.A. (N.A., N.A.)	1.154 (0.445, 2.992) 0.7663	
NOT REPORTED	14	1 (7.1)	N.A. (11.40, N.A.)	5	1 (20.0)	N.A. (0.13, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	3 (1.0)	N.A. (N.A., N.A.)	284	10 (3.5)	N.A. (N.A., N.A.)	0.188 (0.041, 0.859) 0.0157	
AGE CATEGORIZATION								N.M.E.
< 65	71	1 (1.4)	N.M.E.	87	3 (3.4)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	1 (0.7)	N.M.E.	123	5 (4.1)	N.M.E.	N.M.E.	
>= 75	78	1 (1.3)	N.M.E.	74	2 (2.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								N.M.E.
MALE	232	1 (0.4)	N.M.E.	221	3 (1.4)	N.M.E.	N.M.E.	
FEMALE	68	2 (2.9)	N.M.E.	63	7 (11.1)	N.M.E.	N.M.E.	
RACE								>0.9999
WHITE	263	2 (0.8)	N.A. (N.A., N.A.)	233	10 (4.3)	N.A. (N.A., N.A.)	0.176 (0.038, 0.802) 0.0111	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	0	N.M.E.	25	2 (8.0)	N.M.E.	N.M.E.	
EUROPE	175	0	N.M.E.	164	6 (3.7)	N.M.E.	N.M.E.	
ASIA	26	1 (3.8)	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	2 (3.0)	N.M.E.	57	2 (3.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	1 (0.9)	N.M.E.	121	3 (2.5)	N.M.E.	N.M.E.	
>= 1	187	2 (1.1)	N.M.E.	163	7 (4.3)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								N.M.E.
EPITHELIOID	233	1 (0.4)	N.M.E.	219	8 (3.7)	N.M.E.	N.M.E.	
NON-EPITHELIOID	67	2 (3.0)	N.M.E.	65	2 (3.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	1 (8.3)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	0	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	1 (1.0)	N.M.E.	101	2 (2.0)	N.M.E.	N.M.E.	
STAGE IV	158	1 (0.6)	N.M.E.	140	8 (5.7)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	0	N.M.E.	116	4 (3.4)	N.M.E.	N.M.E.	
FORMER	155	3 (1.9)	N.M.E.	153	6 (3.9)	N.M.E.	N.M.E.	
CURRENT	18	0	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9927
YES	28	0	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	N.M.E. 0.2963	
NO	272	3 (1.1)	N.A. (N.A., N.A.)	258	9 (3.5)	N.A. (N.A., N.A.)	0.210 (0.045, 0.971) 0.0273	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	3 (1.0)	N.M.E.	284	10 (3.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Adverse Events with SOC: Skin and Subcutaneous Tissue Disorders and PT: Alopecia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9930
POSITIVE	229	3 (1.3)	N.A. (N.A., N.A.)	203	7 (3.4)	N.A. (N.A., N.A.)	0.250 (0.052, 1.202) 0.0610	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	3 (3.9)	N.A. (N.A., N.A.)	N.M.E. 0.1322	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	138 (46.0)	10.02 (7.85, 15.47)	284	78 (27.5)	N.A. (N.A., N.A.)	1.449 (1.085, 1.936) 0.0117	
AGE CATEGORIZATION								0.2653
< 65	71	33 (46.5)	8.34 (3.71, N.A.)	87	22 (25.3)	N.A. (N.A., N.A.)	1.993 (1.149, 3.456) 0.0124	
>= 65 AND < 75	151	68 (45.0)	12.85 (9.00, 18.60)	123	37 (30.1)	N.A. (N.A., N.A.)	1.074 (0.700, 1.646) 0.7426	
>= 75	78	37 (47.4)	8.08 (5.36, N.A.)	74	19 (25.7)	N.A. (N.A., N.A.)	1.795 (1.016, 3.171) 0.0412	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4971
MALE	232	108 (46.6)	9.30 (6.87, 14.26)	221	59 (26.7)	N.A. (N.A., N.A.)	1.528 (1.098, 2.125) 0.0113	
FEMALE	68	30 (44.1)	15.47 (6.47, N.A.)	63	19 (30.2)	N.A. (N.A., N.A.)	1.204 (0.655, 2.212) 0.5494	
RACE								0.2445
WHITE	263	120 (45.6)	11.89 (7.66, 16.89)	233	63 (27.0)	N.A. (N.A., N.A.)	1.540 (1.124, 2.109) 0.0068	
ASIAN	26	12 (46.2)	7.85 (6.21, 10.02)	38	14 (36.8)	N.A. (4.07, N.A.)	0.555 (0.213, 1.451) 0.2234	
OTHER	11	6 (54.5)	7.92 (0.69, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	5.364 (0.597, 48.198) 0.0931	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.4194
NORTH AMERICA	32	14 (43.8)	9.59 (3.29, N.A.)	25	10 (40.0)	N.A. (3.25, N.A.)	1.015 (0.438, 2.351) 0.9731	
EUROPE	175	83 (47.4)	11.89 (7.66, 16.89)	164	43 (26.2)	N.A. (N.A., N.A.)	1.494 (1.017, 2.196) 0.0398	
ASIA	26	12 (46.2)	7.85 (6.21, 10.02)	38	14 (36.8)	N.A. (4.07, N.A.)	0.555 (0.213, 1.451) 0.2234	
REST OF WORLD	67	29 (43.3)	N.A. (4.24, N.A.)	57	11 (19.3)	N.A. (N.A., N.A.)	2.616 (1.301, 5.260) 0.0051	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.5921
0	113	53 (46.9)	9.89 (6.77, 21.68)	121	31 (25.6)	N.A. (N.A., N.A.)	1.601 (1.009, 2.539) 0.0439	
>= 1	187	85 (45.5)	10.02 (6.87, 15.47)	163	47 (28.8)	N.A. (N.A., N.A.)	1.355 (0.934, 1.966) 0.1081	
IVRS HISTOLOGY								0.8389
EPITHELIOID	233	107 (45.9)	11.99 (7.85, 16.89)	219	60 (27.4)	N.A. (N.A., N.A.)	1.421 (1.021, 1.977) 0.0365	
NON-EPITHELIOID	67	31 (46.3)	8.25 (4.83, 18.60)	65	18 (27.7)	N.A. (N.A., N.A.)	1.569 (0.859, 2.864) 0.1400	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7318
STAGE I	12	3 (25.0)	N.A. (0.66, N.A.)	17	6 (35.3)	N.A. (1.87, N.A.)	0.745 (0.186, 2.983) 0.6742	
STAGE II	23	8 (34.8)	N.A. (4.83, N.A.)	21	5 (23.8)	N.A. (N.A., N.A.)	1.417 (0.449, 4.469) 0.5502	
STAGE III	102	59 (57.8)	8.08 (6.08, 11.99)	101	32 (31.7)	N.A. (N.A., N.A.)	1.449 (0.919, 2.285) 0.1090	
STAGE IV	158	64 (40.5)	13.77 (7.85, N.A.)	140	34 (24.3)	N.A. (N.A., N.A.)	1.477 (0.960, 2.273) 0.0747	
NOT REPORTED	5	4 (80.0)	2.86 (0.26, 3.88)	5	1 (20.0)	N.A. (1.12, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.4507
NEVER	124	48 (38.7)	17.87 (9.89, N.A.)	116	29 (25.0)	N.A. (N.A., N.A.)	1.357 (0.839, 2.196) 0.2123	
FORMER	155	79 (51.0)	7.92 (6.21, 11.89)	153	44 (28.8)	N.A. (N.A., N.A.)	1.522 (1.034, 2.240) 0.0319	
CURRENT	18	10 (55.6)	4.60 (2.37, N.A.)	8	2 (25.0)	N.A. (1.02, N.A.)	2.086 (0.450, 9.660) 0.3364	
UNKNOWN	3	1 (33.3)	N.A. (3.88, N.A.)	7	3 (42.9)	N.A. (0.33, N.A.)	0.476 (0.049, 4.643) 0.5138	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.4838
YES	28	14 (50.0)	8.31 (2.23, N.A.)	26	6 (23.1)	N.A. (N.A., N.A.)	1.996 (0.749, 5.321) 0.1593	
NO	272	124 (45.6)	11.07 (7.85, 16.89)	258	72 (27.9)	N.A. (N.A., N.A.)	1.400 (1.034, 1.897) 0.0291	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	137 (45.8)	N.M.E.	284	78 (27.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Infections and Infestations

Adverse Events with SOC: Infections and Infestations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.6277
POSITIVE	229	106 (46.3)	9.59 (6.83, 17.87)	203	58 (28.6)	N.A. (N.A., N.A.)	1.413 (1.013, 1.970) 0.0408	
NEGATIVE	57	25 (43.9)	15.47 (4.93, N.A.)	76	19 (25.0)	N.A. (N.A., N.A.)	1.640 (0.881, 3.053) 0.1149	
NOT REPORTED	14	7 (50.0)	11.99 (0.62, N.A.)	5	1 (20.0)	N.A. (1.02, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	72 (24.0)	N.A. (N.A., N.A.)	284	75 (26.4)	N.A. (N.A., N.A.)	0.710 (0.505, 0.996) 0.0476	
AGE CATEGORIZATION								0.7748
< 65	71	18 (25.4)	N.A. (16.23, N.A.)	87	21 (24.1)	N.A. (N.A., N.A.)	0.841 (0.433, 1.631) 0.6100	
>= 65 AND < 75	151	33 (21.9)	N.A. (N.A., N.A.)	123	32 (26.0)	N.A. (N.A., N.A.)	0.621 (0.370, 1.042) 0.0694	
>= 75	78	21 (26.9)	N.A. (20.17, N.A.)	74	22 (29.7)	N.A. (N.A., N.A.)	0.740 (0.400, 1.368) 0.3412	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8355
MALE	232	59 (25.4)	N.A. (20.17, N.A.)	221	61 (27.6)	N.A. (N.A., N.A.)	0.723 (0.497, 1.051) 0.0897	
FEMALE	68	13 (19.1)	N.A. (N.A., N.A.)	63	14 (22.2)	N.A. (N.A., N.A.)	0.646 (0.288, 1.449) 0.2847	
RACE								0.9427
WHITE	263	56 (21.3)	N.A. (N.A., N.A.)	233	52 (22.3)	N.A. (N.A., N.A.)	0.769 (0.519, 1.141) 0.1923	
ASIAN	26	13 (50.0)	14.87 (1.64, N.A.)	38	19 (50.0)	N.A. (0.16, N.A.)	0.715 (0.340, 1.503) 0.3912	
OTHER	11	3 (27.3)	N.A. (1.38, N.A.)	13	4 (30.8)	N.A. (1.22, N.A.)	0.590 (0.108, 3.223) 0.5379	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8590
NORTH AMERICA	32	8 (25.0)	N.A. (20.17, N.A.)	25	5 (20.0)	N.A. (N.A., N.A.)	1.111 (0.352, 3.505) 0.8557	
EUROPE	175	37 (21.1)	N.A. (N.A., N.A.)	164	39 (23.8)	N.A. (N.A., N.A.)	0.645 (0.399, 1.042) 0.0723	
ASIA	26	13 (50.0)	14.87 (1.64, N.A.)	38	19 (50.0)	N.A. (0.16, N.A.)	0.715 (0.340, 1.503) 0.3912	
REST OF WORLD	67	14 (20.9)	N.A. (N.A., N.A.)	57	12 (21.1)	N.A. (N.A., N.A.)	0.962 (0.439, 2.109) 0.9225	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.7325
0	113	24 (21.2)	N.A. (20.24, N.A.)	121	27 (22.3)	N.A. (N.A., N.A.)	0.795 (0.450, 1.406) 0.4312	
>= 1	187	48 (25.7)	N.A. (20.17, N.A.)	163	48 (29.4)	N.A. (N.A., N.A.)	0.651 (0.427, 0.994) 0.0461	
IVRS HISTOLOGY								0.3477
EPITHELIOID	233	53 (22.7)	N.A. (N.A., N.A.)	219	51 (23.3)	N.A. (N.A., N.A.)	0.793 (0.532, 1.184) 0.2595	
NON-EPITHELIOID	67	19 (28.4)	N.A. (16.23, N.A.)	65	24 (36.9)	N.A. (2.89, N.A.)	0.527 (0.276, 1.005) 0.0493	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.3271
STAGE I	12	2 (16.7)	N.A. (3.02, N.A.)	17	5 (29.4)	N.A. (1.97, N.A.)	0.553 (0.107, 2.861) 0.4783	
STAGE II	23	5 (21.7)	N.A. (12.25, N.A.)	21	9 (42.9)	N.A. (0.16, N.A.)	0.336 (0.103, 1.092) 0.0574	
STAGE III	102	29 (28.4)	N.A. (19.65, N.A.)	101	22 (21.8)	N.A. (N.A., N.A.)	0.990 (0.552, 1.774) 0.9817	
STAGE IV	158	34 (21.5)	N.A. (N.A., N.A.)	140	39 (27.9)	N.A. (N.A., N.A.)	0.639 (0.397, 1.029) 0.0634	
NOT REPORTED	5	2 (40.0)	10.51 (0.07, 10.51)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.8732
NEVER	124	28 (22.6)	N.A. (N.A., N.A.)	116	25 (21.6)	N.A. (N.A., N.A.)	0.864 (0.494, 1.510) 0.6112	
FORMER	155	39 (25.2)	N.A. (19.65, N.A.)	153	47 (30.7)	N.A. (N.A., N.A.)	0.604 (0.384, 0.951) 0.0285	
CURRENT	18	5 (27.8)	N.A. (4.47, N.A.)	8	3 (37.5)	N.A. (0.13, N.A.)	0.576 (0.136, 2.439) 0.4482	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2465
YES	28	9 (32.1)	20.24 (10.41, N.A.)	26	5 (19.2)	N.A. (N.A., N.A.)	1.200 (0.381, 3.784) 0.7582	
NO	272	63 (23.2)	N.A. (N.A., N.A.)	258	70 (27.1)	N.A. (N.A., N.A.)	0.672 (0.470, 0.959) 0.0280	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	71 (23.7)	N.M.E.	284	75 (26.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Decreased Appetite Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3611
POSITIVE	229	58 (25.3)	N.A. (N.A., N.A.)	203	51 (25.1)	N.A. (N.A., N.A.)	0.798 (0.540, 1.182) 0.2624	
NEGATIVE	57	12 (21.1)	N.A. (17.38, N.A.)	76	23 (30.3)	N.A. (N.A., N.A.)	0.544 (0.259, 1.143) 0.1028	
NOT REPORTED	14	2 (14.3)	N.A. (20.24, N.A.)	5	1 (20.0)	N.A. (1.77, N.A.)	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	4 (1.3)	N.A. (N.A., N.A.)	284	12 (4.2)	N.A. (N.A., N.A.)	0.319 (0.103, 0.990) 0.0368	
AGE CATEGORIZATION								N.M.E.
< 65	71	1 (1.4)	N.M.E.	87	5 (5.7)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	1 (0.7)	N.M.E.	123	5 (4.1)	N.M.E.	N.M.E.	
>= 75	78	2 (2.6)	N.M.E.	74	2 (2.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9921
MALE	232	4 (1.7)	N.A. (N.A., N.A.)	221	10 (4.5)	N.A. (N.A., N.A.)	0.388 (0.122, 1.238) 0.0969	
FEMALE	68	0	N.A. (N.A., N.A.)	63	2 (3.2)	N.A. (N.A., N.A.)	N.M.E. 0.1426	
RACE								>0.9999
WHITE	263	4 (1.5)	N.A. (N.A., N.A.)	233	11 (4.7)	N.A. (N.A., N.A.)	0.324 (0.103, 1.019) 0.0421	
ASIAN	26	0	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.4076	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	2 (6.3)	N.M.E.	25	2 (8.0)	N.M.E.	N.M.E.	
EUROPE	175	0	N.M.E.	164	2 (1.2)	N.M.E.	N.M.E.	
ASIA	26	0	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
REST OF WORLD	67	2 (3.0)	N.M.E.	57	7 (12.3)	N.M.E.	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9897
0	113	0	N.A. (N.A., N.A.)	121	4 (3.3)	N.A. (N.A., N.A.)	N.M.E. 0.0528	
>= 1	187	4 (2.1)	N.A. (N.A., N.A.)	163	8 (4.9)	N.A. (N.A., N.A.)	0.442 (0.133, 1.470) 0.1707	
IVRS HISTOLOGY								0.9920
EPITHELIOID	233	4 (1.7)	N.A. (N.A., N.A.)	219	8 (3.7)	N.A. (N.A., N.A.)	0.481 (0.145, 1.597) 0.2212	
NON-EPITHELIOID	67	0	N.A. (N.A., N.A.)	65	4 (6.2)	N.A. (N.A., N.A.)	N.M.E. 0.0433	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	0	N.M.E.	17	1 (5.9)	N.M.E.	N.M.E.	
STAGE II	23	0	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	2 (2.0)	N.M.E.	101	6 (5.9)	N.M.E.	N.M.E.	
STAGE IV	158	2 (1.3)	N.M.E.	140	4 (2.9)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	1 (20.0)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	0	N.M.E.	116	6 (5.2)	N.M.E.	N.M.E.	
FORMER	155	4 (2.6)	N.M.E.	153	5 (3.3)	N.M.E.	N.M.E.	
CURRENT	18	0	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9920
YES	28	0	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	N.M.E. 0.2963	
NO	272	4 (1.5)	N.A. (N.A., N.A.)	258	11 (4.3)	N.A. (N.A., N.A.)	0.351 (0.112, 1.101) 0.0603	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	4 (1.3)	N.M.E.	284	12 (4.2)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Adverse Events with SOC: Metabolism and Nutrition Disorders and PT: Hypomagnesaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.1933
POSITIVE	229	2 (0.9)	N.A. (N.A., N.A.)	203	9 (4.4)	N.A. (N.A., N.A.)	0.198 (0.043, 0.914) 0.0209	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	3 (3.9)	N.A. (N.A., N.A.)	0.927 (0.155, 5.547) 0.9335	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	118 (39.3)	13.34 (9.63, N.A.)	284	47 (16.5)	N.A. (N.A., N.A.)	2.358 (1.668, 3.334) <0.0001	
AGE CATEGORIZATION								0.0195**
< 65	71	23 (32.4)	N.A. (8.80, N.A.)	87	21 (24.1)	N.A. (N.A., N.A.)	1.268 (0.692, 2.322) 0.4403	
>= 65 AND < 75	151	62 (41.1)	12.85 (9.03, N.A.)	123	17 (13.8)	N.A. (N.A., N.A.)	2.825 (1.629, 4.900) 0.0001	
>= 75	78	33 (42.3)	9.63 (5.13, N.A.)	74	9 (12.2)	N.A. (N.A., N.A.)	4.033 (1.911, 8.514) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6865
MALE	232	88 (37.9)	19.19 (9.63, N.A.)	221	34 (15.4)	N.A. (N.A., N.A.)	2.454 (1.638, 3.678) <0.0001	
FEMALE	68	30 (44.1)	9.92 (4.99, 25.10)	63	13 (20.6)	N.A. (N.A., N.A.)	2.123 (1.085, 4.157) 0.0241	
RACE								0.3252
WHITE	263	107 (40.7)	13.34 (9.17, N.A.)	233	41 (17.6)	N.A. (N.A., N.A.)	2.260 (1.563, 3.268) <0.0001	
ASIAN	26	4 (15.4)	N.A. (9.03, N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	1.264 (0.281, 5.674) 0.7596	
OTHER	11	7 (63.6)	2.69 (0.07, N.A.)	13	2 (15.4)	N.A. (2.63, N.A.)	6.128 (1.263, 29.721) 0.0105	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.3526
NORTH AMERICA	32	16 (50.0)	7.23 (1.91, N.A.)	25	2 (8.0)	N.A. (N.A., N.A.)	6.415 (1.455, 28.297) 0.0048	
EUROPE	175	73 (41.7)	12.71 (8.74, 25.10)	164	31 (18.9)	N.A. (N.A., N.A.)	2.013 (1.302, 3.110) 0.0013	
ASIA	26	4 (15.4)	N.A. (9.03, N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	1.264 (0.281, 5.674) 0.7596	
REST OF WORLD	67	25 (37.3)	N.A. (5.75, N.A.)	57	10 (17.5)	N.A. (N.A., N.A.)	2.527 (1.213, 5.266) 0.0104	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.8913
0	113	46 (40.7)	12.52 (9.03, N.A.)	121	21 (17.4)	N.A. (N.A., N.A.)	2.171 (1.273, 3.700) 0.0035	
>= 1	187	72 (38.5)	19.19 (8.31, N.A.)	163	26 (16.0)	N.A. (N.A., N.A.)	2.490 (1.576, 3.933) <0.0001	
IVRS HISTOLOGY								0.9284
EPITHELIOID	233	94 (40.3)	13.34 (9.63, N.A.)	219	37 (16.9)	N.A. (N.A., N.A.)	2.345 (1.588, 3.464) <0.0001	
NON-EPITHELIOID	67	24 (35.8)	19.19 (6.77, N.A.)	65	10 (15.4)	N.A. (N.A., N.A.)	2.388 (1.124, 5.075) 0.0196	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.1766
STAGE I	12	3 (25.0)	12.52 (6.77, 12.52)	17	3 (17.6)	N.A. (N.A., N.A.)	1.127 (0.187, 6.770) 0.8963	
STAGE II	23	12 (52.2)	6.08 (1.22, N.A.)	21	5 (23.8)	N.A. (N.A., N.A.)	3.066 (1.073, 8.755) 0.0280	
STAGE III	102	48 (47.1)	12.85 (5.45, N.A.)	101	13 (12.9)	N.A. (N.A., N.A.)	3.861 (2.067, 7.214) <0.0001	
STAGE IV	158	51 (32.3)	25.10 (9.92, N.A.)	140	26 (18.6)	N.A. (N.A., N.A.)	1.510 (0.927, 2.461) 0.0951	
NOT REPORTED	5	4 (80.0)	1.35 (0.49, 4.30)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.3803
NEVER	124	44 (35.5)	19.19 (11.99, N.A.)	116	24 (20.7)	N.A. (N.A., N.A.)	1.669 (1.001, 2.784) 0.0471	
FORMER	155	62 (40.0)	13.34 (6.77, N.A.)	153	22 (14.4)	N.A. (N.A., N.A.)	2.973 (1.811, 4.880) <0.0001	
CURRENT	18	10 (55.6)	9.92 (2.76, 19.65)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.0698	
UNKNOWN	3	2 (66.7)	1.22 (0.72, N.A.)	7	1 (14.3)	N.A. (1.48, N.A.)	6.823 (0.585, 79.612) 0.0808	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2537
YES	28	12 (42.9)	8.31 (4.24, N.A.)	26	2 (7.7)	N.A. (N.A., N.A.)	6.443 (1.422, 29.201) 0.0055	
NO	272	106 (39.0)	19.19 (9.92, N.A.)	258	45 (17.4)	N.A. (N.A., N.A.)	2.194 (1.534, 3.138) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	1 (100.0)	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	117 (39.1)	N.M.E.	284	47 (16.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.5122
POSITIVE	229	92 (40.2)	19.19 (8.31, N.A.)	203	36 (17.7)	N.A. (N.A., N.A.)	2.342 (1.583, 3.467) <0.0001	
NEGATIVE	57	22 (38.6)	12.85 (8.80, 25.10)	76	10 (13.2)	N.A. (N.A., N.A.)	2.315 (1.038, 5.161) 0.0347	
NOT REPORTED	14	4 (28.6)	N.A. (0.99, N.A.)	5	1 (20.0)	N.A. (0.03, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	41 (13.7)	N.A. (N.A., N.A.)	284	5 (1.8)	N.A. (N.A., N.A.)	5.992 (2.324, 15.449) <0.0001	
AGE CATEGORIZATION								0.7341
< 65	71	9 (12.7)	N.A. (N.A., N.A.)	87	3 (3.4)	N.A. (N.A., N.A.)	2.937 (0.756, 11.407) 0.1028	
>= 65 AND < 75	151	22 (14.6)	N.A. (N.A., N.A.)	123	2 (1.6)	N.A. (N.A., N.A.)	6.464 (1.478, 28.273) 0.0043	
>= 75	78	10 (12.8)	N.A. (19.19, N.A.)	74	0	N.A. (N.A., N.A.)	N.M.E. 0.0039	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.6344
MALE	232	28 (12.1)	N.A. (N.A., N.A.)	221	4 (1.8)	N.A. (N.A., N.A.)	5.845 (2.021, 16.899) 0.0002	
FEMALE	68	13 (19.1)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	6.530 (0.800, 53.286) 0.0438	
RACE								0.7739
WHITE	263	35 (13.3)	N.A. (N.A., N.A.)	233	4 (1.7)	N.A. (N.A., N.A.)	5.754 (2.002, 16.540) 0.0002	
ASIAN	26	2 (7.7)	N.A. (12.45, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	1.860 (0.116, 29.746) 0.6557	
OTHER	11	4 (36.4)	N.A. (0.92, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.0196	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
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All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8245
NORTH AMERICA	32	6 (18.8)	N.A. (7.85, N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	4.086 (0.477, 34.979) 0.1634	
EUROPE	175	23 (13.1)	N.A. (N.A., N.A.)	164	2 (1.2)	N.A. (N.A., N.A.)	7.892 (1.814, 34.332) 0.0011	
ASIA	26	2 (7.7)	N.A. (12.45, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	1.860 (0.116, 29.746) 0.6557	
REST OF WORLD	67	10 (14.9)	N.A. (N.A., N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	7.065 (0.880, 56.724) 0.0322	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9612
0	113	15 (13.3)	N.A. (N.A., N.A.)	121	2 (1.7)	N.A. (N.A., N.A.)	5.947 (1.316, 26.877) 0.0085	
>= 1	187	26 (13.9)	N.A. (N.A., N.A.)	163	3 (1.8)	N.A. (N.A., N.A.)	5.891 (1.743, 19.911) 0.0012	
IVRS HISTOLOGY								0.3103
EPITHELIOID	233	33 (14.2)	N.A. (N.A., N.A.)	219	3 (1.4)	N.A. (N.A., N.A.)	8.669 (2.622, 28.665) <0.0001	
NON-EPITHELIOID	67	8 (11.9)	N.A. (19.19, N.A.)	65	2 (3.1)	N.A. (N.A., N.A.)	1.970 (0.361, 10.756) 0.4248	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7231
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	6 (26.1)	N.A. (12.45, N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	5.064 (0.591, 43.401) 0.0996	
STAGE III	102	18 (17.6)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	11.399 (1.472, 88.246) 0.0032	
STAGE IV	158	14 (8.9)	N.A. (N.A., N.A.)	140	3 (2.1)	N.A. (N.A., N.A.)	3.226 (0.897, 11.605) 0.0579	
NOT REPORTED	5	3 (60.0)	4.30 (0.72, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.8925
NEVER	124	17 (13.7)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	12.266 (1.595, 94.343) 0.0020	
FORMER	155	21 (13.5)	N.A. (N.A., N.A.)	153	3 (2.0)	N.A. (N.A., N.A.)	5.585 (1.625, 19.192) 0.0021	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
UNKNOWN	3	2 (66.7)	3.65 (0.72, N.A.)	7	1 (14.3)	N.A. (1.48, N.A.)	4.955 (0.446, 55.044) 0.1489	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9894
YES	28	5 (17.9)	N.A. (8.77, N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.0492	
NO	272	36 (13.2)	N.A. (N.A., N.A.)	258	5 (1.9)	N.A. (N.A., N.A.)	5.177 (1.987, 13.490) 0.0002	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	41 (13.7)	N.M.E.	284	5 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Arthralgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.7920
POSITIVE	229	33 (14.4)	N.A. (N.A., N.A.)	203	4 (2.0)	N.A. (N.A., N.A.)	5.495 (1.905, 15.847) 0.0004	
NEGATIVE	57	7 (12.3)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	7.461 (0.872, 63.841) 0.0315	
NOT REPORTED	14	1 (7.1)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	24 (8.0)	N.A. (N.A., N.A.)	284	7 (2.5)	N.A. (N.A., N.A.)	2.568 (1.075, 6.137) 0.0278	
AGE CATEGORIZATION								0.5191
< 65	71	6 (8.5)	N.A. (N.A., N.A.)	87	4 (4.6)	N.A. (N.A., N.A.)	1.558 (0.418, 5.801) 0.5055	
>= 65 AND < 75	151	12 (7.9)	N.A. (N.A., N.A.)	123	2 (1.6)	N.A. (N.A., N.A.)	2.980 (0.623, 14.251) 0.1514	
>= 75	78	6 (7.7)	N.A. (N.A., N.A.)	74	1 (1.4)	N.A. (N.A., N.A.)	6.363 (0.765, 52.914) 0.0493	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7567
MALE	232	19 (8.2)	N.A. (N.A., N.A.)	221	6 (2.7)	N.A. (N.A., N.A.)	2.495 (0.971, 6.414) 0.0496	
FEMALE	68	5 (7.4)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	2.983 (0.309, 28.750) 0.3209	
RACE								0.8879
WHITE	263	21 (8.0)	N.A. (N.A., N.A.)	233	6 (2.6)	N.A. (N.A., N.A.)	2.324 (0.904, 5.976) 0.0715	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	1.528 (0.095, 24.440) 0.7629	
OTHER	11	2 (18.2)	N.A. (0.07, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.1153	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	6 (18.8)	N.A. (7.23, N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.0433	
EUROPE	175	11 (6.3)	N.A. (N.A., N.A.)	164	6 (3.7)	N.A. (N.A., N.A.)	0.937 (0.302, 2.907) 0.9106	
ASIA	26	1 (3.8)	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	1.528 (0.095, 24.440) 0.7629	
REST OF WORLD	67	6 (9.0)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.0191	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9786
0	113	9 (8.0)	N.A. (N.A., N.A.)	121	3 (2.5)	N.A. (N.A., N.A.)	2.541 (0.657, 9.825) 0.1612	
>= 1	187	15 (8.0)	N.A. (N.A., N.A.)	163	4 (2.5)	N.A. (N.A., N.A.)	2.561 (0.818, 8.021) 0.0942	
IVRS HISTOLOGY								0.5154
EPITHELIOID	233	18 (7.7)	N.A. (N.A., N.A.)	219	6 (2.7)	N.A. (N.A., N.A.)	2.149 (0.820, 5.634) 0.1108	
NON-EPITHELIOID	67	6 (9.0)	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	4.952 (0.579, 42.386) 0.1052	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9040
STAGE I	12	0	N.A. (N.A., N.A.)	17	2 (11.8)	N.A. (N.A., N.A.)	N.M.E. 0.2605	
STAGE II	23	5 (21.7)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.0226	
STAGE III	102	11 (10.8)	N.A. (N.A., N.A.)	101	2 (2.0)	N.A. (N.A., N.A.)	4.161 (0.883, 19.605) 0.0501	
STAGE IV	158	8 (5.1)	N.A. (N.A., N.A.)	140	3 (2.1)	N.A. (N.A., N.A.)	1.554 (0.379, 6.382) 0.5379	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.6764
NEVER	124	5 (4.0)	N.A. (N.A., N.A.)	116	3 (2.6)	N.A. (N.A., N.A.)	0.980 (0.198, 4.861) 0.9803	
FORMER	155	15 (9.7)	N.A. (N.A., N.A.)	153	3 (2.0)	N.A. (N.A., N.A.)	4.581 (1.305, 16.081) 0.0090	
CURRENT	18	4 (22.2)	N.A. (8.31, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.2967	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (3.06, N.A.)	N.M.E. 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9080
YES	28	4 (14.3)	N.A. (8.31, N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	2.629 (0.273, 25.317) 0.3846	
NO	272	20 (7.4)	N.A. (N.A., N.A.)	258	6 (2.3)	N.A. (N.A., N.A.)	2.488 (0.968, 6.395) 0.0503	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	24 (8.0)	N.M.E.	284	7 (2.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Adverse Events with SOC: Musculoskeletal and Connective Tissue Disorders and PT: Myalgia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.8136
POSITIVE	229	21 (9.2)	N.A. (N.A., N.A.)	203	6 (3.0)	N.A. (N.A., N.A.)	2.627 (1.038, 6.651) 0.0343	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	1.325 (0.083, 21.176) 0.8420	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	27 (9.0)	N.A. (N.A., N.A.)	284	4 (1.4)	N.A. (N.A., N.A.)	5.028 (1.720, 14.700) 0.0010	
AGE CATEGORIZATION								0.6769
< 65	71	3 (4.2)	N.A. (N.A., N.A.)	87	1 (1.1)	N.A. (N.A., N.A.)	2.556 (0.232, 28.195) 0.4267	
>= 65 AND < 75	151	15 (9.9)	N.A. (N.A., N.A.)	123	1 (0.8)	N.A. (N.A., N.A.)	9.727 (1.257, 75.266) 0.0075	
>= 75	78	9 (11.5)	N.A. (N.A., N.A.)	74	2 (2.7)	N.A. (N.A., N.A.)	3.508 (0.727, 16.916) 0.0951	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9912
MALE	232	23 (9.9)	N.A. (N.A., N.A.)	221	4 (1.8)	N.A. (N.A., N.A.)	4.334 (1.460, 12.866) 0.0040	
FEMALE	68	4 (5.9)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0951	
RACE								0.4079
WHITE	263	23 (8.7)	N.A. (N.A., N.A.)	233	2 (0.9)	N.A. (N.A., N.A.)	8.985 (2.092, 38.584) 0.0003	
ASIAN	26	3 (11.5)	N.A. (14.39, N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	0.932 (0.110, 7.930) 0.9484	
OTHER	11	1 (9.1)	N.A. (15.93, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9526
NORTH AMERICA	32	9 (28.1)	N.A. (13.37, N.A.)	25	2 (8.0)	N.A. (N.A., N.A.)	3.353 (0.711, 15.814) 0.1046	
EUROPE	175	14 (8.0)	N.A. (N.A., N.A.)	164	0	N.A. (N.A., N.A.)	N.M.E. 0.0010	
ASIA	26	3 (11.5)	N.A. (14.39, N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	0.932 (0.110, 7.930) 0.9484	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.3740
0	113	12 (10.6)	N.A. (N.A., N.A.)	121	1 (0.8)	N.A. (N.A., N.A.)	8.991 (1.128, 71.652) 0.0122	
>= 1	187	15 (8.0)	N.A. (N.A., N.A.)	163	3 (1.8)	N.A. (N.A., N.A.)	3.746 (1.056, 13.283) 0.0281	
IVRS HISTOLOGY								0.8009
EPITHELIOID	233	19 (8.2)	N.A. (N.A., N.A.)	219	3 (1.4)	N.A. (N.A., N.A.)	4.290 (1.225, 15.029) 0.0131	
NON-EPITHELIOID	67	8 (11.9)	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	7.508 (0.923, 61.070) 0.0264	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9557
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	3 (13.0)	N.A. (N.A., N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	2.798 (0.291, 26.910) 0.3521	
STAGE III	102	8 (7.8)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	6.238 (0.751, 51.812) 0.0520	
STAGE IV	158	16 (10.1)	N.A. (N.A., N.A.)	140	0	N.A. (N.A., N.A.)	N.M.E. 0.0013	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	2 (40.0)	N.A. (2.07, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9640
NEVER	124	10 (8.1)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	5.961 (0.718, 49.520) 0.0600	
FORMER	155	15 (9.7)	N.A. (N.A., N.A.)	153	3 (2.0)	N.A. (N.A., N.A.)	4.254 (1.202, 15.053) 0.0145	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	1 (33.3)	N.A. (1.87, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9919
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.3545	
NO	272	26 (9.6)	N.A. (N.A., N.A.)	258	4 (1.6)	N.A. (N.A., N.A.)	4.820 (1.641, 14.158) 0.0016	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	27 (9.0)	N.M.E.	284	4 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.2390
POSITIVE	229	19 (8.3)	N.A. (N.A., N.A.)	203	2 (1.0)	N.A. (N.A., N.A.)	6.544 (1.488, 28.771) 0.0042	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	2 (2.6)	N.A. (N.A., N.A.)	1.344 (0.189, 9.542) 0.7667	
NOT REPORTED	14	5 (35.7)	N.A. (3.32, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	24 (8.0)	N.A. (N.A., N.A.)	284	4 (1.4)	N.A. (N.A., N.A.)	4.274 (1.439, 12.689) 0.0044	
AGE CATEGORIZATION								0.8943
< 65	71	5 (7.0)	N.A. (19.98, N.A.)	87	0	N.A. (N.A., N.A.)	N.M.E. 0.0514	
>= 65 AND < 75	151	13 (8.6)	N.A. (N.A., N.A.)	123	2 (1.6)	N.A. (N.A., N.A.)	3.920 (0.849, 18.107) 0.0591	
>= 75	78	6 (7.7)	N.A. (N.A., N.A.)	74	2 (2.7)	N.A. (N.A., N.A.)	2.458 (0.476, 12.681) 0.2668	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9910
MALE	232	18 (7.8)	N.A. (N.A., N.A.)	221	4 (1.8)	N.A. (N.A., N.A.)	3.304 (1.079, 10.116) 0.0265	
FEMALE	68	6 (8.8)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0490	
RACE								0.2515
WHITE	263	20 (7.6)	N.A. (N.A., N.A.)	233	1 (0.4)	N.A. (N.A., N.A.)	14.207 (1.878, 107.460) 0.0007	
ASIAN	26	4 (15.4)	N.A. (13.63, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.017 (0.170, 6.088) 0.9856	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9609
NORTH AMERICA	32	5 (15.6)	N.A. (7.39, N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	2.439 (0.253, 23.457) 0.4252	
EUROPE	175	14 (8.0)	N.A. (N.A., N.A.)	164	0	N.A. (N.A., N.A.)	N.M.E. 0.0006	
ASIA	26	4 (15.4)	N.A. (13.63, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.017 (0.170, 6.088) 0.9856	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.5764
0	113	14 (12.4)	N.A. (N.A., N.A.)	121	2 (1.7)	N.A. (N.A., N.A.)	5.720 (1.257, 26.031) 0.0109	
>= 1	187	10 (5.3)	N.A. (N.A., N.A.)	163	2 (1.2)	N.A. (N.A., N.A.)	3.257 (0.676, 15.691) 0.1190	
IVRS HISTOLOGY								0.0521
EPITHELIOID	233	19 (8.2)	N.A. (N.A., N.A.)	219	1 (0.5)	N.A. (N.A., N.A.)	13.015 (1.704, 99.386) 0.0014	
NON-EPITHELIOID	67	5 (7.5)	N.A. (N.A., N.A.)	65	3 (4.6)	N.A. (N.A., N.A.)	1.305 (0.292, 5.838) 0.7270	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.7882
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	3 (13.0)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.1667	
STAGE III	102	7 (6.9)	N.A. (N.A., N.A.)	101	2 (2.0)	N.A. (N.A., N.A.)	2.035 (0.373, 11.115) 0.4020	
STAGE IV	158	12 (7.6)	N.A. (N.A., N.A.)	140	1 (0.7)	N.A. (N.A., N.A.)	8.370 (1.060, 66.089) 0.0157	
NOT REPORTED	5	2 (40.0)	N.A. (1.31, N.A.)	5	1 (20.0)	N.A. (3.48, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9738
NEVER	124	9 (7.3)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	6.091 (0.733, 50.612) 0.0563	
FORMER	155	14 (9.0)	N.A. (N.A., N.A.)	153	3 (2.0)	N.A. (N.A., N.A.)	3.547 (0.978, 12.864) 0.0399	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9996
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	24 (8.8)	N.A. (N.A., N.A.)	258	4 (1.6)	N.A. (N.A., N.A.)	4.319 (1.454, 12.823) 0.0041	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	24 (8.0)	N.M.E.	284	4 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Amylase Increased

Adverse Events with SOC: Investigations and PT: Amylase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9082
POSITIVE	229	17 (7.4)	N.A. (N.A., N.A.)	203	3 (1.5)	N.A. (N.A., N.A.)	3.373 (0.943, 12.071) 0.0472	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	2.749 (0.249, 30.321) 0.3892	
NOT REPORTED	14	4 (28.6)	N.A. (3.71, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	22 (7.3)	N.A. (N.A., N.A.)	284	4 (1.4)	N.A. (N.A., N.A.)	4.669 (1.588, 13.728) 0.0020	
AGE CATEGORIZATION								0.8159
< 65	71	4 (5.6)	N.A. (N.A., N.A.)	87	1 (1.1)	N.A. (N.A., N.A.)	5.129 (0.573, 45.901) 0.1039	
>= 65 AND < 75	151	11 (7.3)	N.A. (N.A., N.A.)	123	0	N.A. (N.A., N.A.)	N.M.E. 0.0051	
>= 75	78	7 (9.0)	N.A. (N.A., N.A.)	74	3 (4.1)	N.A. (N.A., N.A.)	1.860 (0.465, 7.439) 0.3722	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3348
MALE	232	16 (6.9)	N.A. (N.A., N.A.)	221	2 (0.9)	N.A. (N.A., N.A.)	6.858 (1.558, 30.179) 0.0031	
FEMALE	68	6 (8.8)	N.A. (N.A., N.A.)	63	2 (3.2)	N.A. (N.A., N.A.)	2.394 (0.464, 12.361) 0.2820	
RACE								>0.9999
WHITE	263	22 (8.4)	N.A. (N.A., N.A.)	233	3 (1.3)	N.A. (N.A., N.A.)	5.868 (1.736, 19.833) 0.0012	
ASIAN	26	0	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.4081	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8432
NORTH AMERICA	32	8 (25.0)	N.A. (13.80, N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	5.013 (0.604, 41.638) 0.0976	
EUROPE	175	11 (6.3)	N.A. (N.A., N.A.)	164	1 (0.6)	N.A. (N.A., N.A.)	10.616 (1.370, 82.242) 0.0047	
ASIA	26	0	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.4081	
REST OF WORLD	67	3 (4.5)	N.A. (N.A., N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	1.890 (0.171, 20.849) 0.5972	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9719
0	113	10 (8.8)	N.A. (N.A., N.A.)	121	2 (1.7)	N.A. (N.A., N.A.)	4.945 (1.068, 22.889) 0.0233	
>= 1	187	12 (6.4)	N.A. (N.A., N.A.)	163	2 (1.2)	N.A. (N.A., N.A.)	4.569 (1.001, 20.866) 0.0312	
IVRS HISTOLOGY								0.8625
EPITHELIOID	233	16 (6.9)	N.A. (N.A., N.A.)	219	3 (1.4)	N.A. (N.A., N.A.)	4.542 (1.305, 15.808) 0.0090	
NON-EPITHELIOID	67	6 (9.0)	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	5.104 (0.596, 43.692) 0.0973	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.3393	
STAGE III	102	10 (9.8)	N.A. (N.A., N.A.)	101	3 (3.0)	N.A. (N.A., N.A.)	2.718 (0.721, 10.249) 0.1238	
STAGE IV	158	10 (6.3)	N.A. (N.A., N.A.)	140	0	N.A. (N.A., N.A.)	N.M.E. 0.0038	
NOT REPORTED	5	1 (20.0)	N.A. (1.58, N.A.)	5	1 (20.0)	N.A. (0.66, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.6971
NEVER	124	8 (6.5)	N.A. (N.A., N.A.)	116	3 (2.6)	N.A. (N.A., N.A.)	2.239 (0.579, 8.660) 0.2299	
FORMER	155	11 (7.1)	N.A. (N.A., N.A.)	153	1 (0.7)	N.A. (N.A., N.A.)	9.261 (1.173, 73.120) 0.0101	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5403	
UNKNOWN	3	2 (66.7)	1.87 (1.58, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.0269	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9876
YES	28	0	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	N.M.E. 0.3173	
NO	272	22 (8.1)	N.A. (N.A., N.A.)	258	3 (1.2)	N.A. (N.A., N.A.)	6.262 (1.853, 21.164) 0.0007	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	22 (7.4)	N.M.E.	284	4 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Alanine Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Alanine Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.4525
POSITIVE	229	13 (5.7)	N.A. (N.A., N.A.)	203	3 (1.5)	N.A. (N.A., N.A.)	2.959 (0.814, 10.753) 0.0837	
NEGATIVE	57	7 (12.3)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	10.474 (1.287, 85.220) 0.0063	
NOT REPORTED	14	2 (14.3)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	18 (6.0)	N.A. (N.A., N.A.)	284	3 (1.1)	N.A. (N.A., N.A.)	4.463 (1.282, 15.529) 0.0100	
AGE CATEGORIZATION								N.M.E.
< 65	71	5 (7.0)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	8 (5.3)	N.M.E.	123	0	N.M.E.	N.M.E.	
>= 75	78	5 (6.4)	N.M.E.	74	3 (4.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1595
MALE	232	17 (7.3)	N.A. (N.A., N.A.)	221	2 (0.9)	N.A. (N.A., N.A.)	6.776 (1.540, 29.818) 0.0033	
FEMALE	68	1 (1.5)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.2946	
RACE								0.1568
WHITE	263	17 (6.5)	N.A. (N.A., N.A.)	233	1 (0.4)	N.A. (N.A., N.A.)	11.708 (1.532, 89.490) 0.0026	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	0.710 (0.064, 7.827) 0.7784	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8286
NORTH AMERICA	32	4 (12.5)	N.A. (14.75, N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	2.356 (0.245, 22.647) 0.4443	
EUROPE	175	10 (5.7)	N.A. (N.A., N.A.)	164	0	N.A. (N.A., N.A.)	N.M.E. 0.0060	
ASIA	26	1 (3.8)	N.A. (N.A., N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	0.710 (0.064, 7.827) 0.7784	
REST OF WORLD	67	3 (4.5)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.1871	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.7434
0	113	7 (6.2)	N.A. (N.A., N.A.)	121	1 (0.8)	N.A. (N.A., N.A.)	7.603 (0.935, 61.801) 0.0251	
>= 1	187	11 (5.9)	N.A. (N.A., N.A.)	163	2 (1.2)	N.A. (N.A., N.A.)	3.073 (0.638, 14.792) 0.1401	
IVRS HISTOLOGY								0.9910
EPITHELIOID	233	12 (5.2)	N.A. (N.A., N.A.)	219	0	N.A. (N.A., N.A.)	N.M.E. 0.0021	
NON-EPITHELIOID	67	6 (9.0)	N.A. (N.A., N.A.)	65	3 (4.6)	N.A. (N.A., N.A.)	1.313 (0.294, 5.868) 0.7205	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9464
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	0	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE III	102	8 (7.8)	N.A. (N.A., N.A.)	101	2 (2.0)	N.A. (N.A., N.A.)	2.980 (0.601, 14.765) 0.1601	
STAGE IV	158	9 (5.7)	N.A. (N.A., N.A.)	140	1 (0.7)	N.A. (N.A., N.A.)	6.335 (0.779, 51.497) 0.0474	
NOT REPORTED	5	1 (20.0)	N.A. (1.25, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9925
NEVER	124	7 (5.6)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	5.706 (0.687, 47.381) 0.0678	
FORMER	155	9 (5.8)	N.A. (N.A., N.A.)	153	2 (1.3)	N.A. (N.A., N.A.)	3.492 (0.725, 16.810) 0.0963	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
UNKNOWN	3	1 (33.3)	N.A. (1.87, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9924
YES	28	2 (7.1)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.3469	
NO	272	16 (5.9)	N.A. (N.A., N.A.)	258	3 (1.2)	N.A. (N.A., N.A.)	4.166 (1.187, 14.619) 0.0154	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	18 (6.0)	N.M.E.	284	3 (1.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Adverse Events with SOC: Investigations and PT: Blood Alkaline Phosphatase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.6752
POSITIVE	229	11 (4.8)	N.A. (N.A., N.A.)	203	2 (1.0)	N.A. (N.A., N.A.)	3.546 (0.753, 16.697) 0.0871	
NEGATIVE	57	6 (10.5)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	6.818 (0.796, 58.359) 0.0421	
NOT REPORTED	14	1 (7.1)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	16 (5.3)	N.A. (N.A., N.A.)	284	1 (0.4)	N.A. (N.A., N.A.)	12.723 (1.664, 97.265) 0.0015	
AGE CATEGORIZATION								N.M.E.
< 65	71	1 (1.4)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	9 (6.0)	N.M.E.	123	0	N.M.E.	N.M.E.	
>= 75	78	6 (7.7)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9914
MALE	232	9 (3.9)	N.A. (N.A., N.A.)	221	1 (0.5)	N.A. (N.A., N.A.)	7.669 (0.959, 61.316) 0.0232	
FEMALE	68	7 (10.3)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0237	
RACE								>0.9999
WHITE	263	16 (6.1)	N.A. (N.A., N.A.)	233	0	N.A. (N.A., N.A.)	N.M.E. 0.0005	
ASIAN	26	0	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.4081	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	4 (12.5)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	8 (4.6)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	0	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
REST OF WORLD	67	4 (6.0)	N.M.E.	57	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	8 (7.1)	N.M.E.	121	0	N.M.E.	N.M.E.	
>= 1	187	8 (4.3)	N.M.E.	163	1 (0.6)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								0.9918
EPITHELIOID	233	13 (5.6)	N.A. (N.A., N.A.)	219	0	N.A. (N.A., N.A.)	N.M.E. 0.0018	
NON-EPITHELIOID	67	3 (4.5)	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	3.015 (0.314, 28.984) 0.3150	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	0	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE III	102	5 (4.9)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	3.001 (0.312, 28.856) 0.3173	
STAGE IV	158	11 (7.0)	N.A. (N.A., N.A.)	140	0	N.A. (N.A., N.A.)	N.M.E. 0.0023	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	8 (6.5)	N.M.E.	116	1 (0.9)	N.M.E.	N.M.E.	
FORMER	155	6 (3.9)	N.M.E.	153	0	N.M.E.	N.M.E.	
CURRENT	18	1 (5.6)	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	1 (33.3)	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9995
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	16 (5.9)	N.A. (N.A., N.A.)	258	1 (0.4)	N.A. (N.A., N.A.)	12.852 (1.681, 98.246) 0.0014	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	16 (5.4)	N.M.E.	284	1 (0.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Aspartate Aminotransferase Increased

Adverse Events with SOC: Investigations and PT: Aspartate Aminotransferase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9909
POSITIVE	229	9 (3.9)	N.A. (N.A., N.A.)	203	1 (0.5)	N.A. (N.A., N.A.)	6.207 (0.764, 50.451) 0.0505	
NEGATIVE	57	6 (10.5)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.0068	
NOT REPORTED	14	1 (7.1)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	15 (5.0)	N.A. (N.A., N.A.)	284	22 (7.7)	N.A. (N.A., N.A.)	0.384 (0.177, 0.830) 0.0115	
AGE CATEGORIZATION								0.2923
< 65	71	5 (7.0)	N.A. (N.A., N.A.)	87	4 (4.6)	N.A. (N.A., N.A.)	0.636 (0.120, 3.353) 0.5903	
>= 65 AND < 75	151	6 (4.0)	N.A. (N.A., N.A.)	123	10 (8.1)	N.A. (N.A., N.A.)	0.407 (0.139, 1.191) 0.0900	
>= 75	78	4 (5.1)	N.A. (22.34, N.A.)	74	8 (10.8)	N.A. (N.A., N.A.)	0.223 (0.047, 1.052) 0.0377	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7921
MALE	232	10 (4.3)	N.A. (N.A., N.A.)	221	16 (7.2)	N.A. (N.A., N.A.)	0.298 (0.111, 0.803) 0.0112	
FEMALE	68	5 (7.4)	N.A. (N.A., N.A.)	63	6 (9.5)	N.A. (N.A., N.A.)	0.608 (0.171, 2.154) 0.4357	
RACE								0.2746
WHITE	263	11 (4.2)	N.A. (N.A., N.A.)	233	17 (7.3)	N.A. (N.A., N.A.)	0.311 (0.124, 0.781) 0.0087	
ASIAN	26	4 (15.4)	N.A. (11.10, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.517 (0.306, 7.518) 0.6118	
OTHER	11	0	N.A. (N.A., N.A.)	13	2 (15.4)	N.A. (1.71, N.A.)	N.M.E. 0.1869	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.3105
NORTH AMERICA	32	1 (3.1)	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	0.753 (0.047, 12.049) 0.8409	
EUROPE	175	6 (3.4)	N.A. (N.A., N.A.)	164	13 (7.9)	N.A. (N.A., N.A.)	0.088 (0.016, 0.481) 0.0007	
ASIA	26	4 (15.4)	N.A. (11.10, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	1.517 (0.306, 7.518) 0.6118	
REST OF WORLD	67	4 (6.0)	N.A. (N.A., N.A.)	57	5 (8.8)	N.A. (N.A., N.A.)	0.708 (0.190, 2.639) 0.6077	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.4359
0	113	5 (4.4)	N.A. (N.A., N.A.)	121	11 (9.1)	N.A. (N.A., N.A.)	0.295 (0.085, 1.024) 0.0419	
>= 1	187	10 (5.3)	N.A. (N.A., N.A.)	163	11 (6.7)	N.A. (N.A., N.A.)	0.473 (0.175, 1.279) 0.1313	
IVRS HISTOLOGY								0.2377
EPITHELIOID	233	10 (4.3)	N.A. (N.A., N.A.)	219	18 (8.2)	N.A. (N.A., N.A.)	0.260 (0.098, 0.689) 0.0036	
NON-EPITHELIOID	67	5 (7.5)	N.A. (N.A., N.A.)	65	4 (6.2)	N.A. (N.A., N.A.)	0.977 (0.244, 3.908) 0.9757	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.3762
STAGE I	12	1 (8.3)	N.A. (N.A., N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	1.374 (0.086, 21.980) 0.8214	
STAGE II	23	3 (13.0)	N.A. (22.34, N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	0.934 (0.058, 14.927) 0.9612	
STAGE III	102	5 (4.9)	N.A. (N.A., N.A.)	101	7 (6.9)	N.A. (N.A., N.A.)	0.569 (0.167, 1.945) 0.3615	
STAGE IV	158	6 (3.8)	N.A. (N.A., N.A.)	140	13 (9.3)	N.A. (N.A., N.A.)	0.196 (0.056, 0.689) 0.0046	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.3645
NEVER	124	3 (2.4)	N.A. (N.A., N.A.)	116	10 (8.6)	N.A. (N.A., N.A.)	0.183 (0.040, 0.833) 0.0136	
FORMER	155	12 (7.7)	N.A. (N.A., N.A.)	153	11 (7.2)	N.A. (N.A., N.A.)	0.631 (0.245, 1.622) 0.3348	
CURRENT	18	0	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (0.95, N.A.)	N.M.E. 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.7927
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	0.878 (0.055, 14.050) 0.9270	
NO	272	14 (5.1)	N.A. (N.A., N.A.)	258	21 (8.1)	N.A. (N.A., N.A.)	0.358 (0.159, 0.806) 0.0096	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	15 (5.0)	N.M.E.	284	22 (7.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Dysgeusia

Adverse Events with SOC: Nervous System Disorders and PT: Dysgeusia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3354
POSITIVE	229	14 (6.1)	N.A. (N.A., N.A.)	203	15 (7.4)	N.A. (N.A., N.A.)	0.522 (0.229, 1.192) 0.1161	
NEGATIVE	57	1 (1.8)	N.A. (22.34, N.A.)	76	5 (6.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0544	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	2 (40.0)	N.A. (0.20, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	3 (1.0)	N.A. (N.A., N.A.)	284	15 (5.3)	N.A. (N.A., N.A.)	0.128 (0.029, 0.560) 0.0012	
AGE CATEGORIZATION								N.M.E.
< 65	71	3 (4.2)	N.M.E.	87	6 (6.9)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	0	N.M.E.	123	7 (5.7)	N.M.E.	N.M.E.	
>= 75	78	0	N.M.E.	74	2 (2.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9927
MALE	232	3 (1.3)	N.A. (N.A., N.A.)	221	14 (6.3)	N.A. (N.A., N.A.)	0.137 (0.031, 0.605) 0.0021	
FEMALE	68	0	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	N.M.E. 0.3317	
RACE								>0.9999
WHITE	263	3 (1.1)	N.A. (N.A., N.A.)	233	13 (5.6)	N.A. (N.A., N.A.)	0.137 (0.031, 0.607) 0.0021	
ASIAN	26	0	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	N.M.E. 0.4142	
OTHER	11	0	N.A. (N.A., N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	N.M.E. 0.3938	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	0	N.M.E.	25	1 (4.0)	N.M.E.	N.M.E.	
EUROPE	175	0	N.M.E.	164	8 (4.9)	N.M.E.	N.M.E.	
ASIA	26	0	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
REST OF WORLD	67	3 (4.5)	N.M.E.	57	5 (8.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9890
0	113	0	N.A. (N.A., N.A.)	121	6 (5.0)	N.A. (N.A., N.A.)	N.M.E. 0.0180	
>= 1	187	3 (1.6)	N.A. (N.A., N.A.)	163	9 (5.5)	N.A. (N.A., N.A.)	0.194 (0.042, 0.897) 0.0191	
IVRS HISTOLOGY								0.9993
EPITHELIOID	233	3 (1.3)	N.A. (N.A., N.A.)	219	15 (6.8)	N.A. (N.A., N.A.)	0.127 (0.029, 0.556) 0.0011	
NON-EPITHELIOID	67	0	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	0	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	0	N.M.E.	21	2 (9.5)	N.M.E.	N.M.E.	
STAGE III	102	1 (1.0)	N.M.E.	101	8 (7.9)	N.M.E.	N.M.E.	
STAGE IV	158	2 (1.3)	N.M.E.	140	5 (3.6)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.7067
NEVER	124	2 (1.6)	N.A. (N.A., N.A.)	116	4 (3.4)	N.A. (N.A., N.A.)	0.239 (0.027, 2.139) 0.1639	
FORMER	155	1 (0.6)	N.A. (N.A., N.A.)	153	10 (6.5)	N.A. (N.A., N.A.)	0.102 (0.013, 0.794) 0.0072	
CURRENT	18	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (1.58, N.A.)	N.M.E. 0.1336	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9893
YES	28	0	N.A. (N.A., N.A.)	26	3 (11.5)	N.A. (N.A., N.A.)	N.M.E. 0.0645	
NO	272	3 (1.1)	N.A. (N.A., N.A.)	258	12 (4.7)	N.A. (N.A., N.A.)	0.162 (0.036, 0.726) 0.0065	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	3 (1.0)	N.M.E.	284	15 (5.3)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders. PT: Neuropathy Peripheral

Adverse Events with SOC: Nervous System Disorders and PT: Neuropathy Peripheral Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9922
POSITIVE	229	3 (1.3)	N.A. (N.A., N.A.)	203	10 (4.9)	N.A. (N.A., N.A.)	0.177 (0.039, 0.808) 0.0116	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	5 (6.6)	N.A. (N.A., N.A.)	N.M.E. 0.0634	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	66 (22.0)	N.A. (N.A., N.A.)	284	170 (59.9)	2.63 (2.07, 3.38)	0.223 (0.164, 0.304) <0.0001	
AGE CATEGORIZATION								0.2985
< 65	71	16 (22.5)	N.A. (N.A., N.A.)	87	44 (50.6)	3.71 (2.73, N.A.)	0.356 (0.198, 0.641) 0.0003	
>= 65 AND < 75	151	30 (19.9)	N.A. (19.32, N.A.)	123	78 (63.4)	2.10 (1.84, 3.48)	0.140 (0.085, 0.230) <0.0001	
>= 75	78	20 (25.6)	N.A. (16.49, N.A.)	74	48 (64.9)	2.07 (1.38, 2.79)	0.277 (0.162, 0.472) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9519
MALE	232	50 (21.6)	N.A. (N.A., N.A.)	221	131 (59.3)	2.73 (2.07, 3.61)	0.218 (0.153, 0.311) <0.0001	
FEMALE	68	16 (23.5)	N.A. (19.32, N.A.)	63	39 (61.9)	2.10 (1.45, 3.48)	0.240 (0.128, 0.451) <0.0001	
RACE								0.3204
WHITE	263	54 (20.5)	N.A. (N.A., N.A.)	233	135 (57.9)	2.76 (2.10, 3.68)	0.224 (0.160, 0.315) <0.0001	
ASIAN	26	11 (42.3)	15.47 (3.48, N.A.)	38	27 (71.1)	1.54 (0.95, 2.14)	0.308 (0.139, 0.684) 0.0022	
OTHER	11	1 (9.1)	N.A. (6.21, N.A.)	13	8 (61.5)	3.78 (0.49, N.A.)	0.096 (0.012, 0.774) 0.0065	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.2650
NORTH AMERICA	32	9 (28.1)	N.A. (N.A., N.A.)	25	14 (56.0)	2.73 (1.94, N.A.)	0.459 (0.198, 1.064) 0.0620	
EUROPE	175	33 (18.9)	N.A. (N.A., N.A.)	164	99 (60.4)	2.66 (2.00, 3.55)	0.192 (0.126, 0.293) <0.0001	
ASIA	26	11 (42.3)	15.47 (3.48, N.A.)	38	27 (71.1)	1.54 (0.95, 2.14)	0.308 (0.139, 0.684) 0.0022	
REST OF WORLD	67	13 (19.4)	N.A. (N.A., N.A.)	57	30 (52.6)	3.94 (2.07, N.A.)	0.196 (0.093, 0.414) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.6417
0	113	25 (22.1)	N.A. (19.32, N.A.)	121	69 (57.0)	3.09 (2.07, N.A.)	0.217 (0.130, 0.362) <0.0001	
>= 1	187	41 (21.9)	N.A. (N.A., N.A.)	163	101 (62.0)	2.10 (2.04, 3.06)	0.225 (0.153, 0.331) <0.0001	
IVRS HISTOLOGY								0.7000
EPITHELIOID	233	50 (21.5)	N.A. (N.A., N.A.)	219	126 (57.5)	2.79 (2.10, 3.94)	0.231 (0.162, 0.329) <0.0001	
NON-EPITHELIOID	67	16 (23.9)	N.A. (17.74, N.A.)	65	44 (67.7)	2.07 (1.41, 2.76)	0.201 (0.107, 0.376) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.5121
STAGE I	12	0	N.A. (N.A., N.A.)	17	7 (41.2)	N.A. (2.10, N.A.)	N.M.E. 0.0184	
STAGE II	23	0	N.A. (N.A., N.A.)	21	11 (52.4)	3.91 (1.64, N.A.)	N.M.E. <0.0001	
STAGE III	102	23 (22.5)	N.A. (N.A., N.A.)	101	65 (64.4)	2.07 (1.41, 3.45)	0.177 (0.103, 0.302) <0.0001	
STAGE IV	158	41 (25.9)	N.A. (16.49, N.A.)	140	84 (60.0)	2.73 (2.04, 3.68)	0.287 (0.193, 0.427) <0.0001	
NOT REPORTED	5	2 (40.0)	N.A. (0.39, N.A.)	5	3 (60.0)	2.09 (0.66, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.7647
NEVER	124	28 (22.6)	N.A. (19.32, N.A.)	116	71 (61.2)	2.69 (2.04, 3.91)	0.223 (0.138, 0.361) <0.0001	
FORMER	155	32 (20.6)	N.A. (N.A., N.A.)	153	92 (60.1)	2.14 (2.07, 3.38)	0.203 (0.131, 0.314) <0.0001	
CURRENT	18	6 (33.3)	N.A. (4.86, N.A.)	8	4 (50.0)	N.A. (0.23, N.A.)	0.505 (0.141, 1.815) 0.2878	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	3 (42.9)	3.71 (0.26, N.A.)	N.M.E. 0.1506	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1741
YES	28	8 (28.6)	20.27 (19.32, N.A.)	26	12 (46.2)	4.34 (1.08, N.A.)	0.338 (0.123, 0.929) 0.0275	
NO	272	58 (21.3)	N.A. (N.A., N.A.)	258	158 (61.2)	2.14 (2.07, 3.06)	0.215 (0.155, 0.297) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	66 (22.1)	N.M.E.	284	170 (59.9)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3982
POSITIVE	229	47 (20.5)	N.A. (N.A., N.A.)	203	124 (61.1)	2.10 (2.07, 3.45)	0.201 (0.140, 0.289) <0.0001	
NEGATIVE	57	14 (24.6)	N.A. (N.A., N.A.)	76	43 (56.6)	2.71 (1.41, N.A.)	0.324 (0.174, 0.604) 0.0002	
NOT REPORTED	14	5 (35.7)	19.32 (13.34, N.A.)	5	3 (60.0)	6.77 (1.35, 6.77)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	44 (14.7)	N.A. (N.A., N.A.)	284	120 (42.3)	N.A. (6.77, N.A.)	0.262 (0.182, 0.377) <0.0001	
AGE CATEGORIZATION								0.0622
< 65	71	12 (16.9)	N.A. (N.A., N.A.)	87	27 (31.0)	N.A. (N.A., N.A.)	0.483 (0.240, 0.975) 0.0375	
>= 65 AND < 75	151	16 (10.6)	N.A. (N.A., N.A.)	123	57 (46.3)	N.A. (3.48, N.A.)	0.129 (0.068, 0.247) <0.0001	
>= 75	78	16 (20.5)	N.A. (N.A., N.A.)	74	36 (48.6)	4.11 (2.10, N.A.)	0.361 (0.200, 0.651) 0.0004	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1746
MALE	232	30 (12.9)	N.A. (N.A., N.A.)	221	96 (43.4)	N.A. (4.11, N.A.)	0.231 (0.150, 0.354) <0.0001	
FEMALE	68	14 (20.6)	N.A. (N.A., N.A.)	63	24 (38.1)	N.A. (2.76, N.A.)	0.384 (0.188, 0.785) 0.0065	
RACE								0.9829
WHITE	263	38 (14.4)	N.A. (N.A., N.A.)	233	94 (40.3)	N.A. (N.A., N.A.)	0.276 (0.185, 0.410) <0.0001	
ASIAN	26	6 (23.1)	N.A. (17.74, N.A.)	38	21 (55.3)	2.79 (1.94, N.A.)	0.293 (0.110, 0.780) 0.0087	
OTHER	11	0	N.A. (N.A., N.A.)	13	5 (38.5)	N.A. (1.77, N.A.)	N.M.E. 0.0259	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.2559
NORTH AMERICA	32	9 (28.1)	N.A. (N.A., N.A.)	25	11 (44.0)	N.A. (2.10, N.A.)	0.637 (0.264, 1.540) 0.3075	
EUROPE	175	20 (11.4)	N.A. (N.A., N.A.)	164	68 (41.5)	N.A. (4.24, N.A.)	0.212 (0.126, 0.357) <0.0001	
ASIA	26	6 (23.1)	N.A. (17.74, N.A.)	38	21 (55.3)	2.79 (1.94, N.A.)	0.293 (0.110, 0.780) 0.0087	
REST OF WORLD	67	9 (13.4)	N.A. (N.A., N.A.)	57	20 (35.1)	N.A. (6.77, N.A.)	0.229 (0.092, 0.571) 0.0006	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.2427
0	113	18 (15.9)	N.A. (N.A., N.A.)	121	46 (38.0)	N.A. (N.A., N.A.)	0.294 (0.162, 0.536) <0.0001	
>= 1	187	26 (13.9)	N.A. (N.A., N.A.)	163	74 (45.4)	N.A. (2.79, N.A.)	0.240 (0.151, 0.380) <0.0001	
IVRS HISTOLOGY								0.3489
EPITHELIOID	233	34 (14.6)	N.A. (N.A., N.A.)	219	86 (39.3)	N.A. (N.A., N.A.)	0.293 (0.193, 0.443) <0.0001	
NON-EPITHELIOID	67	10 (14.9)	N.A. (17.74, N.A.)	65	34 (52.3)	2.79 (1.94, N.A.)	0.190 (0.088, 0.412) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.8674
STAGE I	12	0	N.A. (N.A., N.A.)	17	6 (35.3)	N.A. (2.10, N.A.)	N.M.E. 0.0311	
STAGE II	23	0	N.A. (N.A., N.A.)	21	8 (38.1)	N.A. (2.46, N.A.)	N.M.E. 0.0014	
STAGE III	102	16 (15.7)	N.A. (N.A., N.A.)	101	46 (45.5)	N.A. (3.25, N.A.)	0.213 (0.113, 0.403) <0.0001	
STAGE IV	158	26 (16.5)	N.A. (N.A., N.A.)	140	58 (41.4)	N.A. (4.11, N.A.)	0.334 (0.207, 0.538) <0.0001	
NOT REPORTED	5	2 (40.0)	N.A. (0.39, N.A.)	5	2 (40.0)	N.A. (1.38, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.7818
NEVER	124	20 (16.1)	N.A. (N.A., N.A.)	116	49 (42.2)	N.A. (3.91, N.A.)	0.274 (0.156, 0.482) <0.0001	
FORMER	155	20 (12.9)	N.A. (N.A., N.A.)	153	66 (43.1)	N.A. (3.52, N.A.)	0.233 (0.138, 0.392) <0.0001	
CURRENT	18	4 (22.2)	N.A. (4.86, N.A.)	8	3 (37.5)	N.A. (0.23, N.A.)	0.504 (0.112, 2.271) 0.3636	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	2 (28.6)	N.A. (1.38, N.A.)	N.M.E. 0.2649	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.3876
YES	28	5 (17.9)	N.A. (19.32, N.A.)	26	9 (34.6)	N.A. (3.25, N.A.)	0.388 (0.120, 1.261) 0.1023	
NO	272	39 (14.3)	N.A. (N.A., N.A.)	258	111 (43.0)	N.A. (4.17, N.A.)	0.253 (0.172, 0.371) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	44 (14.7)	N.M.E.	284	120 (42.3)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.4823
POSITIVE	229	31 (13.5)	N.A. (N.A., N.A.)	203	87 (42.9)	N.A. (3.88, N.A.)	0.246 (0.160, 0.376) <0.0001	
NEGATIVE	57	9 (15.8)	N.A. (N.A., N.A.)	76	30 (39.5)	N.A. (3.98, N.A.)	0.369 (0.175, 0.778) 0.0065	
NOT REPORTED	14	4 (28.6)	19.32 (13.34, N.A.)	5	3 (60.0)	6.77 (1.35, 6.77)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	6 (2.0)	N.A. (N.A., N.A.)	284	79 (27.8)	N.A. (N.A., N.A.)	0.041 (0.015, 0.112) <0.0001	
AGE CATEGORIZATION								0.9376
< 65	71	0	N.A. (N.A., N.A.)	87	21 (24.1)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
>= 65 AND < 75	151	4 (2.6)	N.A. (N.A., N.A.)	123	31 (25.2)	N.A. (N.A., N.A.)	0.046 (0.011, 0.192) <0.0001	
>= 75	78	2 (2.6)	N.A. (N.A., N.A.)	74	27 (36.5)	N.A. (3.61, N.A.)	0.057 (0.013, 0.239) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5806
MALE	232	4 (1.7)	N.A. (N.A., N.A.)	221	62 (28.1)	N.A. (N.A., N.A.)	0.026 (0.006, 0.107) <0.0001	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	17 (27.0)	N.A. (N.A., N.A.)	0.093 (0.021, 0.403) <0.0001	
RACE								0.9447
WHITE	263	5 (1.9)	N.A. (N.A., N.A.)	233	61 (26.2)	N.A. (N.A., N.A.)	0.050 (0.018, 0.138) <0.0001	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	13 (34.2)	N.A. (3.48, N.A.)	<0.001 (<0.001, N.A.) 0.0011	
OTHER	11	0	N.A. (N.A., N.A.)	13	5 (38.5)	N.A. (0.49, N.A.)	N.M.E. 0.0218	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9862
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	3 (12.0)	N.A. (N.A., N.A.)	N.M.E. 0.0411	
EUROPE	175	4 (2.3)	N.A. (N.A., N.A.)	164	49 (29.9)	N.A. (N.A., N.A.)	0.063 (0.023, 0.175) <0.0001	
ASIA	26	1 (3.8)	N.A. (N.A., N.A.)	38	13 (34.2)	N.A. (3.48, N.A.)	<0.001 (<0.001, N.A.) 0.0011	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	14 (24.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.1839
0	113	1 (0.9)	N.A. (N.A., N.A.)	121	39 (32.2)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) <0.0001	
>= 1	187	5 (2.7)	N.A. (N.A., N.A.)	163	40 (24.5)	N.A. (N.A., N.A.)	0.076 (0.027, 0.213) <0.0001	
IVRS HISTOLOGY								0.3949
EPITHELIOID	233	4 (1.7)	N.A. (N.A., N.A.)	219	63 (28.8)	N.A. (N.A., N.A.)	0.038 (0.012, 0.121) <0.0001	
NON-EPITHELIOID	67	2 (3.0)	N.A. (N.A., N.A.)	65	16 (24.6)	N.A. (N.A., N.A.)	0.053 (0.007, 0.402) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9950
STAGE I	12	0	N.A. (N.A., N.A.)	17	4 (23.5)	N.A. (3.48, N.A.)	N.M.E. 0.1042	
STAGE II	23	0	N.A. (N.A., N.A.)	21	6 (28.6)	N.A. (4.17, N.A.)	N.M.E. 0.0067	
STAGE III	102	3 (2.9)	N.A. (N.A., N.A.)	101	36 (35.6)	N.A. (N.A., N.A.)	0.045 (0.011, 0.186) <0.0001	
STAGE IV	158	3 (1.9)	N.A. (N.A., N.A.)	140	32 (22.9)	N.A. (N.A., N.A.)	0.049 (0.012, 0.204) <0.0001	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (0.66, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9993
NEVER	124	3 (2.4)	N.A. (N.A., N.A.)	116	35 (30.2)	N.A. (N.A., N.A.)	0.045 (0.011, 0.189) <0.0001	
FORMER	155	3 (1.9)	N.A. (N.A., N.A.)	153	42 (27.5)	N.A. (N.A., N.A.)	0.041 (0.010, 0.168) <0.0001	
CURRENT	18	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.49, N.A.)	N.M.E. 0.1336	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (0.26, N.A.)	N.M.E. 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1049
YES	28	2 (7.1)	N.A. (N.A., N.A.)	26	7 (26.9)	N.A. (3.61, N.A.)	0.212 (0.044, 1.023) 0.0335	
NO	272	4 (1.5)	N.A. (N.A., N.A.)	258	72 (27.9)	N.A. (N.A., N.A.)	0.023 (0.006, 0.092) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	6 (2.0)	N.M.E.	284	79 (27.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.5601
POSITIVE	229	5 (2.2)	N.A. (N.A., N.A.)	203	51 (25.1)	N.A. (N.A., N.A.)	0.045 (0.014, 0.144) <0.0001	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	28 (36.8)	N.A. (N.A., N.A.)	0.039 (0.005, 0.289) <0.0001	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	5 (1.7)	N.A. (N.A., N.A.)	284	32 (11.3)	N.A. (N.A., N.A.)	0.114 (0.040, 0.322) <0.0001	
AGE CATEGORIZATION								0.6472
< 65	71	1 (1.4)	N.A. (N.A., N.A.)	87	6 (6.9)	N.A. (N.A., N.A.)	0.203 (0.024, 1.683) 0.1010	
>= 65 AND < 75	151	1 (0.7)	N.A. (N.A., N.A.)	123	12 (9.8)	N.A. (N.A., N.A.)	0.067 (0.009, 0.516) 0.0005	
>= 75	78	3 (3.8)	N.A. (N.A., N.A.)	74	14 (18.9)	N.A. (N.A., N.A.)	0.121 (0.027, 0.531) 0.0008	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4515
MALE	232	3 (1.3)	N.A. (N.A., N.A.)	221	25 (11.3)	N.A. (N.A., N.A.)	0.074 (0.017, 0.311) <0.0001	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	7 (11.1)	N.A. (N.A., N.A.)	0.251 (0.052, 1.211) 0.0627	
RACE								0.9702
WHITE	263	4 (1.5)	N.A. (N.A., N.A.)	233	21 (9.0)	N.A. (N.A., N.A.)	0.124 (0.037, 0.415) <0.0001	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	6 (15.8)	N.A. (N.A., N.A.)	0.235 (0.028, 1.952) 0.1440	
OTHER	11	0	N.A. (N.A., N.A.)	13	5 (38.5)	N.A. (1.91, N.A.)	N.M.E. 0.0259	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9548
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	N.M.E. 0.2579	
EUROPE	175	3 (1.7)	N.A. (N.A., N.A.)	164	21 (12.8)	N.A. (N.A., N.A.)	0.085 (0.020, 0.361) <0.0001	
ASIA	26	1 (3.8)	N.A. (N.A., N.A.)	38	6 (15.8)	N.A. (N.A., N.A.)	0.235 (0.028, 1.952) 0.1440	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	4 (7.0)	N.A. (N.A., N.A.)	0.224 (0.025, 2.003) 0.1423	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.5220
0	113	1 (0.9)	N.A. (N.A., N.A.)	121	13 (10.7)	N.A. (N.A., N.A.)	0.078 (0.010, 0.598) 0.0015	
>= 1	187	4 (2.1)	N.A. (N.A., N.A.)	163	19 (11.7)	N.A. (N.A., N.A.)	0.134 (0.040, 0.454) 0.0001	
IVRS HISTOLOGY								0.9414
EPITHELIOID	233	4 (1.7)	N.A. (N.A., N.A.)	219	25 (11.4)	N.A. (N.A., N.A.)	0.109 (0.033, 0.361) <0.0001	
NON-EPITHELIOID	67	1 (1.5)	N.A. (N.A., N.A.)	65	7 (10.8)	N.A. (N.A., N.A.)	0.132 (0.016, 1.071) 0.0254	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.8138
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	0	N.A. (N.A., N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	N.M.E. 0.0689	
STAGE III	102	2 (2.0)	N.A. (N.A., N.A.)	101	18 (17.8)	N.A. (N.A., N.A.)	0.100 (0.023, 0.431) 0.0001	
STAGE IV	158	3 (1.9)	N.A. (N.A., N.A.)	140	11 (7.9)	N.A. (N.A., N.A.)	0.158 (0.035, 0.715) 0.0060	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9599
NEVER	124	2 (1.6)	N.A. (N.A., N.A.)	116	11 (9.5)	N.A. (N.A., N.A.)	0.168 (0.037, 0.757) 0.0082	
FORMER	155	2 (1.3)	N.A. (N.A., N.A.)	153	19 (12.4)	N.A. (N.A., N.A.)	0.050 (0.007, 0.373) <0.0001	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	2 (25.0)	N.A. (1.35, N.A.)	0.221 (0.020, 2.436) 0.1758	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1840
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	0.852 (0.053, 13.616) 0.9095	
NO	272	4 (1.5)	N.A. (N.A., N.A.)	258	31 (12.0)	N.A. (N.A., N.A.)	0.088 (0.027, 0.289) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	5 (1.7)	N.M.E.	284	32 (11.3)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9629
POSITIVE	229	4 (1.7)	N.A. (N.A., N.A.)	203	23 (11.3)	N.A. (N.A., N.A.)	0.110 (0.033, 0.368) <0.0001	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	9 (11.8)	N.A. (N.A., N.A.)	0.147 (0.019, 1.158) 0.0346	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
OVERALL	300	0	N.A. (N.A., N.A.)	284	25 (8.8)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
AGE CATEGORIZATION								>0.9999
< 65	71	0	N.A. (N.A., N.A.)	87	5 (5.7)	N.A. (N.A., N.A.)	N.M.E. 0.0426	
>= 65 AND < 75	151	0	N.A. (N.A., N.A.)	123	13 (10.6)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
>= 75	78	0	N.A. (N.A., N.A.)	74	7 (9.5)	N.A. (N.A., N.A.)	N.M.E. 0.0054	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9998
MALE	232	0	N.A. (N.A., N.A.)	221	22 (10.0)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
FEMALE	68	0	N.A. (N.A., N.A.)	63	3 (4.8)	N.A. (N.A., N.A.)	N.M.E. 0.0666	
RACE								>0.9999
WHITE	263	0	N.A. (N.A., N.A.)	233	18 (7.7)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
ASIAN	26	0	N.A. (N.A., N.A.)	38	7 (18.4)	N.A. (N.A., N.A.)	N.M.E. 0.0229	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	3 (12.0)	N.A. (N.A., N.A.)	N.M.E. 0.0446	
EUROPE	175	0	N.A. (N.A., N.A.)	164	13 (7.9)	N.A. (N.A., N.A.)	N.M.E. 0.0001	
ASIA	26	0	N.A. (N.A., N.A.)	38	7 (18.4)	N.A. (N.A., N.A.)	N.M.E. 0.0229	
REST OF WORLD	67	0	N.A. (N.A., N.A.)	57	2 (3.5)	N.A. (N.A., N.A.)	N.M.E. 0.1186	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								>0.9999
0	113	0	N.A. (N.A., N.A.)	121	10 (8.3)	N.A. (N.A., N.A.)	N.M.E. 0.0018	
>= 1	187	0	N.A. (N.A., N.A.)	163	15 (9.2)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
IVRS HISTOLOGY								>0.9999
EPITHELIOID	233	0	N.A. (N.A., N.A.)	219	18 (8.2)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
NON-EPITHELIOID	67	0	N.A. (N.A., N.A.)	65	7 (10.8)	N.A. (N.A., N.A.)	N.M.E. 0.0064	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	0	N.A. (N.A., N.A.)	21	2 (9.5)	N.A. (N.A., N.A.)	N.M.E. 0.1380	
STAGE III	102	0	N.A. (N.A., N.A.)	101	7 (6.9)	N.A. (N.A., N.A.)	N.M.E. 0.0067	
STAGE IV	158	0	N.A. (N.A., N.A.)	140	14 (10.0)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	2 (40.0)	N.A. (0.66, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	0	N.A. (N.A., N.A.)	116	9 (7.8)	N.A. (N.A., N.A.)	N.M.E. 0.0016	
FORMER	155	0	N.A. (N.A., N.A.)	153	15 (9.8)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
CURRENT	18	0	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (0.26, N.A.)	N.M.E. 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9975
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	0	N.A. (N.A., N.A.)	258	25 (9.7)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	0	N.M.E.	284	25 (8.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Adverse Events with SOC: Blood and Lymphatic System Disorders and PT: Leukopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9998
POSITIVE	229	0	N.A. (N.A., N.A.)	203	20 (9.9)	N.A. (N.A., N.A.)	N.M.E. <0.0001	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	4 (5.3)	N.A. (N.A., N.A.)	N.M.E. 0.0846	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (6.77, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	58 (19.3)	N.A. (N.A., N.A.)	284	7 (2.5)	N.A. (N.A., N.A.)	7.656 (3.474, 16.873) <0.0001	
AGE CATEGORIZATION								0.6136
< 65	71	12 (16.9)	N.A. (20.76, N.A.)	87	2 (2.3)	N.A. (N.A., N.A.)	5.877 (1.269, 27.213) 0.0101	
>= 65 AND < 75	151	29 (19.2)	N.A. (N.A., N.A.)	123	4 (3.3)	N.A. (N.A., N.A.)	5.659 (1.970, 16.259) 0.0003	
>= 75	78	17 (21.8)	N.A. (N.A., N.A.)	74	1 (1.4)	N.A. (N.A., N.A.)	18.260 (2.430, 137.214) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5675
MALE	232	44 (19.0)	N.A. (N.A., N.A.)	221	6 (2.7)	N.A. (N.A., N.A.)	6.677 (2.822, 15.795) <0.0001	
FEMALE	68	14 (20.6)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	13.297 (1.738, 101.718) 0.0012	
RACE								0.9249
WHITE	263	49 (18.6)	N.A. (N.A., N.A.)	233	6 (2.6)	N.A. (N.A., N.A.)	7.305 (3.115, 17.128) <0.0001	
ASIAN	26	7 (26.9)	10.94 (7.39, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	7.008 (0.794, 61.821) 0.0437	
OTHER	11	2 (18.2)	N.A. (2.04, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.0840	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8689
NORTH AMERICA	32	8 (25.0)	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	6.737 (0.841, 53.958) 0.0377	
EUROPE	175	32 (18.3)	N.A. (N.A., N.A.)	164	3 (1.8)	N.A. (N.A., N.A.)	9.915 (3.019, 32.560) <0.0001	
ASIA	26	7 (26.9)	10.94 (7.39, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	7.008 (0.794, 61.821) 0.0437	
REST OF WORLD	67	11 (16.4)	N.A. (N.A., N.A.)	57	2 (3.5)	N.A. (N.A., N.A.)	4.771 (1.045, 21.785) 0.0260	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.7921
0	113	25 (22.1)	N.A. (N.A., N.A.)	121	3 (2.5)	N.A. (N.A., N.A.)	8.711 (2.609, 29.090) <0.0001	
>= 1	187	33 (17.6)	N.A. (N.A., N.A.)	163	4 (2.5)	N.A. (N.A., N.A.)	6.977 (2.451, 19.861) <0.0001	
IVRS HISTOLOGY								0.6097
EPITHELIOID	233	45 (19.3)	N.A. (N.A., N.A.)	219	6 (2.7)	N.A. (N.A., N.A.)	6.920 (2.933, 16.324) <0.0001	
NON-EPITHELIOID	67	13 (19.4)	N.A. (10.94, N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	11.783 (1.521, 91.305) 0.0027	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9946
STAGE I	12	1 (8.3)	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. 0.2340	
STAGE II	23	3 (13.0)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.0739	
STAGE III	102	25 (24.5)	N.A. (N.A., N.A.)	101	3 (3.0)	N.A. (N.A., N.A.)	7.773 (2.317, 26.082) <0.0001	
STAGE IV	158	29 (18.4)	N.A. (N.A., N.A.)	140	4 (2.9)	N.A. (N.A., N.A.)	6.249 (2.182, 17.901) <0.0001	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.7391
NEVER	124	22 (17.7)	N.A. (N.A., N.A.)	116	2 (1.7)	N.A. (N.A., N.A.)	10.515 (2.456, 45.017) <0.0001	
FORMER	155	30 (19.4)	N.A. (N.A., N.A.)	153	4 (2.6)	N.A. (N.A., N.A.)	6.890 (2.398, 19.795) <0.0001	
CURRENT	18	5 (27.8)	N.A. (6.24, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.1360	
UNKNOWN	3	1 (33.3)	N.A. (1.87, N.A.)	7	1 (14.3)	N.A. (0.03, N.A.)	1.972 (0.122, 31.838) 0.6259	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9870
YES	28	5 (17.9)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.0287	
NO	272	53 (19.5)	N.A. (N.A., N.A.)	258	7 (2.7)	N.A. (N.A., N.A.)	6.959 (3.141, 15.415) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	58 (19.4)	N.M.E.	284	7 (2.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9213
POSITIVE	229	51 (22.3)	N.A. (N.A., N.A.)	203	6 (3.0)	N.A. (N.A., N.A.)	7.137 (3.041, 16.751) <0.0001	
NEGATIVE	57	5 (8.8)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	7.480 (0.873, 64.118) 0.0309	
NOT REPORTED	14	2 (14.3)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	38 (12.7)	N.A. (N.A., N.A.)	284	3 (1.1)	N.A. (N.A., N.A.)	11.769 (3.615, 38.318) <0.0001	
AGE CATEGORIZATION								0.8754
< 65	71	10 (14.1)	N.A. (17.02, N.A.)	87	1 (1.1)	N.A. (N.A., N.A.)	9.094 (1.118, 73.958) 0.0121	
>= 65 AND < 75	151	16 (10.6)	N.A. (N.A., N.A.)	123	2 (1.6)	N.A. (N.A., N.A.)	6.657 (1.523, 29.090) 0.0036	
>= 75	78	12 (15.4)	N.A. (N.A., N.A.)	74	0	N.A. (N.A., N.A.)	N.M.E. 0.0004	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9896
MALE	232	26 (11.2)	N.A. (N.A., N.A.)	221	3 (1.4)	N.A. (N.A., N.A.)	7.975 (2.395, 26.555) <0.0001	
FEMALE	68	12 (17.6)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0009	
RACE								0.9999
WHITE	263	35 (13.3)	N.A. (N.A., N.A.)	233	3 (1.3)	N.A. (N.A., N.A.)	10.682 (3.275, 34.840) <0.0001	
ASIAN	26	2 (7.7)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.2199	
OTHER	11	1 (9.1)	N.A. (17.02, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8521
NORTH AMERICA	32	7 (21.9)	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	5.990 (0.734, 48.868) 0.0575	
EUROPE	175	21 (12.0)	N.A. (N.A., N.A.)	164	1 (0.6)	N.A. (N.A., N.A.)	19.221 (2.572, 143.620) <0.0001	
ASIA	26	2 (7.7)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.2199	
REST OF WORLD	67	8 (11.9)	N.A. (N.A., N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	6.733 (0.828, 54.749) 0.0389	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.6497
0	113	16 (14.2)	N.A. (N.A., N.A.)	121	1 (0.8)	N.A. (N.A., N.A.)	17.520 (2.317, 132.475) 0.0001	
>= 1	187	22 (11.8)	N.A. (N.A., N.A.)	163	2 (1.2)	N.A. (N.A., N.A.)	9.054 (2.108, 38.895) 0.0003	
IVRS HISTOLOGY								0.9897
EPITHELIOID	233	30 (12.9)	N.A. (N.A., N.A.)	219	3 (1.4)	N.A. (N.A., N.A.)	9.275 (2.814, 30.573) <0.0001	
NON-EPITHELIOID	67	8 (11.9)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.0072	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9659
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.2918	
STAGE III	102	18 (17.6)	N.A. (N.A., N.A.)	101	2 (2.0)	N.A. (N.A., N.A.)	9.359 (2.161, 40.538) 0.0003	
STAGE IV	158	19 (12.0)	N.A. (N.A., N.A.)	140	1 (0.7)	N.A. (N.A., N.A.)	15.064 (2.000, 113.462) 0.0004	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.5774
NEVER	124	15 (12.1)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	13.446 (1.758, 102.842) 0.0011	
FORMER	155	18 (11.6)	N.A. (N.A., N.A.)	153	1 (0.7)	N.A. (N.A., N.A.)	17.526 (2.326, 132.047) 0.0001	
CURRENT	18	4 (22.2)	N.A. (6.24, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.1978	
UNKNOWN	3	1 (33.3)	N.A. (2.07, N.A.)	7	1 (14.3)	N.A. (0.03, N.A.)	1.972 (0.122, 31.838) 0.6259	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9903
YES	28	3 (10.7)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.0958	
NO	272	35 (12.9)	N.A. (N.A., N.A.)	258	3 (1.2)	N.A. (N.A., N.A.)	10.810 (3.305, 35.359) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	38 (12.7)	N.M.E.	284	3 (1.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hypothyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hypothyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9895
POSITIVE	229	34 (14.8)	N.A. (N.A., N.A.)	203	3 (1.5)	N.A. (N.A., N.A.)	9.615 (2.934, 31.508) <0.0001	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.0344	
NOT REPORTED	14	1 (7.1)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	12 (4.0)	N.A. (N.A., N.A.)	284	2 (0.7)	N.A. (N.A., N.A.)	5.840 (1.307, 26.089) 0.0087	
AGE CATEGORIZATION								N.M.E.
< 65	71	2 (2.8)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	3 (2.0)	N.M.E.	123	2 (1.6)	N.M.E.	N.M.E.	
>= 75	78	7 (9.0)	N.M.E.	74	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9934
MALE	232	10 (4.3)	N.A. (N.A., N.A.)	221	2 (0.9)	N.A. (N.A., N.A.)	4.940 (1.082, 22.545) 0.0221	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.1720	
RACE								>0.9999
WHITE	263	9 (3.4)	N.A. (N.A., N.A.)	233	2 (0.9)	N.A. (N.A., N.A.)	4.073 (0.880, 18.850) 0.0515	
ASIAN	26	2 (7.7)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0778	
OTHER	11	1 (9.1)	N.A. (5.52, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.2100	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	2 (6.3)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	7 (4.0)	N.M.E.	164	1 (0.6)	N.M.E.	N.M.E.	
ASIA	26	2 (7.7)	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	1 (1.5)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	5 (4.4)	N.M.E.	121	1 (0.8)	N.M.E.	N.M.E.	
>= 1	187	7 (3.7)	N.M.E.	163	1 (0.6)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								0.9930
EPITHELIOID	233	9 (3.9)	N.A. (N.A., N.A.)	219	2 (0.9)	N.A. (N.A., N.A.)	4.288 (0.926, 19.845) 0.0423	
NON-EPITHELIOID	67	3 (4.5)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.0859	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	1 (8.3)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	0	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	4 (3.9)	N.M.E.	101	0	N.M.E.	N.M.E.	
STAGE IV	158	7 (4.4)	N.M.E.	140	2 (1.4)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	5 (4.0)	N.M.E.	116	0	N.M.E.	N.M.E.	
FORMER	155	5 (3.2)	N.M.E.	153	2 (1.3)	N.M.E.	N.M.E.	
CURRENT	18	1 (5.6)	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	1 (33.3)	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9936
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.3276	
NO	272	11 (4.0)	N.A. (N.A., N.A.)	258	2 (0.8)	N.A. (N.A., N.A.)	5.391 (1.195, 24.321) 0.0139	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	12 (4.0)	N.M.E.	284	2 (0.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders. PT: Hyperthyroidism

Adverse Events with SOC: Endocrine Disorders and PT: Hyperthyroidism Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.4728
POSITIVE	229	10 (4.4)	N.A. (N.A., N.A.)	203	1 (0.5)	N.A. (N.A., N.A.)	9.022 (1.155, 70.481) 0.0109	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	2.783 (0.252, 30.705) 0.3829	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	51 (17.0)	N.A. (N.A., N.A.)	284	13 (4.6)	N.A. (N.A., N.A.)	2.900 (1.543, 5.450) 0.0005	
AGE CATEGORIZATION								0.7686
< 65	71	11 (15.5)	N.A. (22.34, N.A.)	87	5 (5.7)	N.A. (N.A., N.A.)	1.841 (0.584, 5.801) 0.2907	
>= 65 AND < 75	151	29 (19.2)	N.A. (N.A., N.A.)	123	5 (4.1)	N.A. (N.A., N.A.)	3.391 (1.269, 9.063) 0.0098	
>= 75	78	11 (14.1)	N.A. (N.A., N.A.)	74	3 (4.1)	N.A. (N.A., N.A.)	3.697 (1.031, 13.255) 0.0316	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.7971
MALE	232	40 (17.2)	N.A. (N.A., N.A.)	221	10 (4.5)	N.A. (N.A., N.A.)	3.287 (1.616, 6.686) 0.0005	
FEMALE	68	11 (16.2)	N.A. (N.A., N.A.)	63	3 (4.8)	N.A. (N.A., N.A.)	1.703 (0.419, 6.923) 0.4514	
RACE								0.9440
WHITE	263	44 (16.7)	N.A. (N.A., N.A.)	233	8 (3.4)	N.A. (N.A., N.A.)	3.574 (1.641, 7.784) 0.0006	
ASIAN	26	7 (26.9)	N.A. (6.18, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	3.919 (1.013, 15.171) 0.0331	
OTHER	11	0	N.A. (N.A., N.A.)	13	2 (15.4)	N.A. (1.58, N.A.)	N.M.E. 0.1869	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9875
NORTH AMERICA	32	7 (21.9)	N.A. (9.30, N.A.)	25	2 (8.0)	N.A. (N.A., N.A.)	2.477 (0.500, 12.276) 0.2504	
EUROPE	175	25 (14.3)	N.A. (N.A., N.A.)	164	8 (4.9)	N.A. (N.A., N.A.)	1.860 (0.793, 4.362) 0.1482	
ASIA	26	7 (26.9)	N.A. (6.18, N.A.)	38	3 (7.9)	N.A. (N.A., N.A.)	3.919 (1.013, 15.171) 0.0331	
REST OF WORLD	67	12 (17.9)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.0031	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.8887
0	113	22 (19.5)	N.A. (N.A., N.A.)	121	6 (5.0)	N.A. (N.A., N.A.)	3.069 (1.203, 7.832) 0.0137	
>= 1	187	29 (15.5)	N.A. (N.A., N.A.)	163	7 (4.3)	N.A. (N.A., N.A.)	2.797 (1.191, 6.569) 0.0137	
IVRS HISTOLOGY								0.5860
EPITHELIOID	233	39 (16.7)	N.A. (N.A., N.A.)	219	9 (4.1)	N.A. (N.A., N.A.)	3.162 (1.495, 6.688) 0.0015	
NON-EPITHELIOID	67	12 (17.9)	N.A. (N.A., N.A.)	65	4 (6.2)	N.A. (N.A., N.A.)	2.249 (0.692, 7.304) 0.1658	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9463
STAGE I	12	3 (25.0)	11.93 (11.93, 11.96)	17	1 (5.9)	N.A. (N.A., N.A.)	1.882 (0.114, 30.941) 0.6530	
STAGE II	23	3 (13.0)	N.A. (9.69, N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	2.007 (0.182, 22.162) 0.5617	
STAGE III	102	19 (18.6)	N.A. (N.A., N.A.)	101	6 (5.9)	N.A. (N.A., N.A.)	2.509 (0.968, 6.500) 0.0504	
STAGE IV	158	24 (15.2)	N.A. (N.A., N.A.)	140	5 (3.6)	N.A. (N.A., N.A.)	3.373 (1.253, 9.079) 0.0106	
NOT REPORTED	5	2 (40.0)	N.A. (0.03, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.1068
NEVER	124	21 (16.9)	N.A. (N.A., N.A.)	116	5 (4.3)	N.A. (N.A., N.A.)	3.268 (1.202, 8.888) 0.0143	
FORMER	155	27 (17.4)	N.A. (N.A., N.A.)	153	6 (3.9)	N.A. (N.A., N.A.)	3.379 (1.350, 8.459) 0.0058	
CURRENT	18	2 (11.1)	N.A. (22.34, N.A.)	8	2 (25.0)	N.A. (1.41, N.A.)	0.193 (0.017, 2.133) 0.1342	
UNKNOWN	3	1 (33.3)	N.A. (0.49, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9860
YES	28	5 (17.9)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.0509	
NO	272	46 (16.9)	N.A. (N.A., N.A.)	258	13 (5.0)	N.A. (N.A., N.A.)	2.600 (1.370, 4.932) 0.0024	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	51 (17.1)	N.M.E.	284	13 (4.6)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications

Adverse Events with SOC: Injury, Poisoning and Procedural Complications Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.6391
POSITIVE	229	40 (17.5)	N.A. (N.A., N.A.)	203	11 (5.4)	N.A. (N.A., N.A.)	2.666 (1.342, 5.296) 0.0036	
NEGATIVE	57	7 (12.3)	N.A. (22.34, N.A.)	76	2 (2.6)	N.A. (N.A., N.A.)	2.802 (0.513, 15.303) 0.2139	
NOT REPORTED	14	4 (28.6)	N.A. (9.63, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	25 (8.3)	N.A. (N.A., N.A.)	284	2 (0.7)	N.A. (N.A., N.A.)	11.328 (2.671, 48.049) <0.0001	
AGE CATEGORIZATION								>0.9999
< 65	71	6 (8.5)	N.A. (N.A., N.A.)	87	2 (2.3)	N.A. (N.A., N.A.)	3.211 (0.623, 16.550) 0.1399	
>= 65 AND < 75	151	13 (8.6)	N.A. (N.A., N.A.)	123	0	N.A. (N.A., N.A.)	N.M.E. 0.0014	
>= 75	78	6 (7.7)	N.A. (N.A., N.A.)	74	0	N.A. (N.A., N.A.)	N.M.E. 0.0158	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.4101
MALE	232	19 (8.2)	N.A. (N.A., N.A.)	221	1 (0.5)	N.A. (N.A., N.A.)	18.822 (2.519, 140.607) <0.0001	
FEMALE	68	6 (8.8)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	3.777 (0.422, 33.792) 0.2012	
RACE								>0.9999
WHITE	263	22 (8.4)	N.A. (N.A., N.A.)	233	2 (0.9)	N.A. (N.A., N.A.)	9.210 (2.152, 39.403) 0.0003	
ASIAN	26	3 (11.5)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0329	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	4 (12.5)	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.0745	
EUROPE	175	11 (6.3)	N.A. (N.A., N.A.)	164	2 (1.2)	N.A. (N.A., N.A.)	4.761 (1.043, 21.729) 0.0262	
ASIA	26	3 (11.5)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0329	
REST OF WORLD	67	7 (10.4)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.0181	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.8958
0	113	10 (8.8)	N.A. (N.A., N.A.)	121	1 (0.8)	N.A. (N.A., N.A.)	11.126 (1.424, 86.923) 0.0038	
>= 1	187	15 (8.0)	N.A. (N.A., N.A.)	163	1 (0.6)	N.A. (N.A., N.A.)	11.800 (1.544, 90.205) 0.0024	
IVRS HISTOLOGY								0.9915
EPITHELIOID	233	20 (8.6)	N.A. (N.A., N.A.)	219	2 (0.9)	N.A. (N.A., N.A.)	9.294 (2.165, 39.906) 0.0003	
NON-EPITHELIOID	67	5 (7.5)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.0450	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	2 (16.7)	11.96 (11.96, N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. 0.2340	
STAGE II	23	2 (8.7)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.1614	
STAGE III	102	9 (8.8)	N.A. (N.A., N.A.)	101	0	N.A. (N.A., N.A.)	N.M.E. 0.0024	
STAGE IV	158	11 (7.0)	N.A. (N.A., N.A.)	140	2 (1.4)	N.A. (N.A., N.A.)	4.605 (1.009, 21.018) 0.0301	
NOT REPORTED	5	1 (20.0)	N.A. (0.03, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.3533
NEVER	124	13 (10.5)	N.A. (N.A., N.A.)	116	0	N.A. (N.A., N.A.)	N.M.E. 0.0006	
FORMER	155	10 (6.5)	N.A. (N.A., N.A.)	153	1 (0.7)	N.A. (N.A., N.A.)	9.171 (1.162, 72.396) 0.0105	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (1.41, N.A.)	0.416 (0.026, 6.659) 0.5220	
UNKNOWN	3	1 (33.3)	N.A. (0.49, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
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Subgroup Time-Adjusted Analyses of Adverse Events
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All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9920
YES	28	2 (7.1)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.1780	
NO	272	23 (8.5)	N.A. (N.A., N.A.)	258	2 (0.8)	N.A. (N.A., N.A.)	10.404 (2.439, 44.375) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	25 (8.4)	N.M.E.	284	2 (0.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Injury, Poisoning and Procedural Complications. PT: Infusion Related Reaction

Adverse Events with SOC: Injury, Poisoning and Procedural Complications and PT: Infusion Related Reaction Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3379
POSITIVE	229	20 (8.7)	N.A. (N.A., N.A.)	203	1 (0.5)	N.A. (N.A., N.A.)	17.496 (2.342, 130.701) 0.0001	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	2.731 (0.248, 30.127) 0.3924	
NOT REPORTED	14	2 (14.3)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	42 (14.0)	N.A. (N.A., N.A.)	284	16 (5.6)	N.A. (N.A., N.A.)	1.965 (1.079, 3.578) 0.0244	
AGE CATEGORIZATION								0.0692
< 65	71	6 (8.5)	N.A. (N.A., N.A.)	87	8 (9.2)	N.A. (N.A., N.A.)	0.610 (0.184, 2.025) 0.4150	
>= 65 AND < 75	151	18 (11.9)	N.A. (N.A., N.A.)	123	5 (4.1)	N.A. (N.A., N.A.)	2.182 (0.780, 6.109) 0.1274	
>= 75	78	18 (23.1)	N.A. (21.29, N.A.)	74	3 (4.1)	N.A. (N.A., N.A.)	5.154 (1.490, 17.821) 0.0039	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5741
MALE	232	36 (15.5)	N.A. (N.A., N.A.)	221	13 (5.9)	N.A. (N.A., N.A.)	2.216 (1.152, 4.263) 0.0144	
FEMALE	68	6 (8.8)	N.A. (N.A., N.A.)	63	3 (4.8)	N.A. (N.A., N.A.)	0.951 (0.199, 4.553) 0.9502	
RACE								0.9080
WHITE	263	36 (13.7)	N.A. (N.A., N.A.)	233	15 (6.4)	N.A. (N.A., N.A.)	1.708 (0.913, 3.196) 0.0899	
ASIAN	26	3 (11.5)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0840	
OTHER	11	3 (27.3)	N.A. (5.45, N.A.)	13	1 (7.7)	N.A. (N.A., N.A.)	2.553 (0.230, 28.343) 0.4289	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9733
NORTH AMERICA	32	5 (15.6)	N.A. (10.35, N.A.)	25	2 (8.0)	N.A. (N.A., N.A.)	1.251 (0.209, 7.503) 0.8058	
EUROPE	175	27 (15.4)	N.A. (N.A., N.A.)	164	12 (7.3)	N.A. (N.A., N.A.)	1.755 (0.870, 3.540) 0.1114	
ASIA	26	3 (11.5)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0840	
REST OF WORLD	67	7 (10.4)	N.A. (N.A., N.A.)	57	2 (3.5)	N.A. (N.A., N.A.)	2.282 (0.442, 11.769) 0.3114	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Chemo N	Patients with Event n (%)	KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.3104
0	113	11 (9.7)	N.A. (N.A., N.A.)	121	7 (5.8)	N.A. (N.A., N.A.)	1.071 (0.376, 3.055) 0.8965	
>= 1	187	31 (16.6)	N.A. (N.A., N.A.)	163	9 (5.5)	N.A. (N.A., N.A.)	2.559 (1.195, 5.481) 0.0122	
IVRS HISTOLOGY								0.3330
EPITHELIOID	233	34 (14.6)	N.A. (N.A., N.A.)	219	11 (5.0)	N.A. (N.A., N.A.)	2.323 (1.149, 4.698) 0.0156	
NON-EPITHELIOID	67	8 (11.9)	N.A. (21.29, N.A.)	65	5 (7.7)	N.A. (N.A., N.A.)	1.142 (0.348, 3.744) 0.8255	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9425
STAGE I	12	1 (8.3)	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. 0.2340	
STAGE II	23	4 (17.4)	N.A. (10.35, N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.0873	
STAGE III	102	13 (12.7)	N.A. (N.A., N.A.)	101	7 (6.9)	N.A. (N.A., N.A.)	1.315 (0.494, 3.501) 0.5819	
STAGE IV	158	24 (15.2)	N.A. (N.A., N.A.)	140	9 (6.4)	N.A. (N.A., N.A.)	1.923 (0.870, 4.251) 0.0998	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9805
NEVER	124	18 (14.5)	N.A. (N.A., N.A.)	116	8 (6.9)	N.A. (N.A., N.A.)	1.724 (0.725, 4.102) 0.2123	
FORMER	155	20 (12.9)	N.A. (N.A., N.A.)	153	7 (4.6)	N.A. (N.A., N.A.)	2.043 (0.825, 5.063) 0.1149	
CURRENT	18	4 (22.2)	N.A. (5.29, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.1708	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (2.10, N.A.)	N.M.E. 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.1130
YES	28	4 (14.3)	N.A. (16.33, N.A.)	26	4 (15.4)	N.A. (N.A., N.A.)	0.661 (0.148, 2.952) 0.5845	
NO	272	38 (14.0)	N.A. (N.A., N.A.)	258	12 (4.7)	N.A. (N.A., N.A.)	2.400 (1.225, 4.699) 0.0084	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	42 (14.0)	N.M.E.	284	16 (5.6)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Cardiac Disorders

Adverse Events with SOC: Cardiac Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.0400**
POSITIVE	229	27 (11.8)	N.A. (N.A., N.A.)	203	14 (6.9)	N.A. (N.A., N.A.)	1.271 (0.642, 2.517) 0.4898	
NEGATIVE	57	12 (21.1)	N.A. (N.A., N.A.)	76	2 (2.6)	N.A. (N.A., N.A.)	8.234 (1.830, 37.037) 0.0011	
NOT REPORTED	14	3 (21.4)	N.A. (14.36, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	39 (13.0)	N.A. (N.A., N.A.)	284	5 (1.8)	N.A. (N.A., N.A.)	5.321 (2.051, 13.804) 0.0001	
AGE CATEGORIZATION								0.1818
< 65	71	9 (12.7)	N.A. (16.56, N.A.)	87	1 (1.1)	N.A. (N.A., N.A.)	7.532 (0.907, 62.553) 0.0276	
>= 65 AND < 75	151	23 (15.2)	N.A. (N.A., N.A.)	123	1 (0.8)	N.A. (N.A., N.A.)	13.803 (1.831, 104.042) 0.0008	
>= 75	78	7 (9.0)	N.A. (N.A., N.A.)	74	3 (4.1)	N.A. (N.A., N.A.)	1.617 (0.392, 6.679) 0.5046	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9835
MALE	232	29 (12.5)	N.A. (N.A., N.A.)	221	5 (2.3)	N.A. (N.A., N.A.)	3.742 (1.400, 10.007) 0.0048	
FEMALE	68	10 (14.7)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0051	
RACE								0.2815
WHITE	263	29 (11.0)	N.A. (N.A., N.A.)	233	1 (0.4)	N.A. (N.A., N.A.)	18.671 (2.507, 139.034) <0.0001	
ASIAN	26	9 (34.6)	18.20 (12.71, N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	2.604 (0.762, 8.902) 0.1115	
OTHER	11	1 (9.1)	N.A. (16.56, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.6976
NORTH AMERICA	32	2 (6.3)	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.2185	
EUROPE	175	18 (10.3)	N.A. (N.A., N.A.)	164	1 (0.6)	N.A. (N.A., N.A.)	9.794 (1.258, 76.245) 0.0075	
ASIA	26	9 (34.6)	18.20 (12.71, N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	2.604 (0.762, 8.902) 0.1115	
REST OF WORLD	67	10 (14.9)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.0060	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9130
0	113	13 (11.5)	N.A. (N.A., N.A.)	121	2 (1.7)	N.A. (N.A., N.A.)	6.661 (1.493, 29.726) 0.0041	
>= 1	187	26 (13.9)	N.A. (N.A., N.A.)	163	3 (1.8)	N.A. (N.A., N.A.)	4.552 (1.319, 15.712) 0.0085	
IVRS HISTOLOGY								0.4891
EPITHELIOID	233	26 (11.2)	N.A. (N.A., N.A.)	219	4 (1.8)	N.A. (N.A., N.A.)	4.418 (1.497, 13.035) 0.0033	
NON-EPITHELIOID	67	13 (19.4)	N.A. (16.56, N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	9.189 (1.164, 72.551) 0.0104	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9041
STAGE I	12	3 (25.0)	N.A. (0.85, N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	5.305 (0.548, 51.382) 0.1076	
STAGE II	23	3 (13.0)	N.A. (12.71, N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.3393	
STAGE III	102	15 (14.7)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	9.284 (1.177, 73.238) 0.0100	
STAGE IV	158	18 (11.4)	N.A. (N.A., N.A.)	140	3 (2.1)	N.A. (N.A., N.A.)	4.234 (1.219, 14.709) 0.0135	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9500
NEVER	124	13 (10.5)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	6.889 (0.849, 55.907) 0.0361	
FORMER	155	24 (15.5)	N.A. (N.A., N.A.)	153	4 (2.6)	N.A. (N.A., N.A.)	4.715 (1.598, 13.917) 0.0020	
CURRENT	18	2 (11.1)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.4499	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9900
YES	28	3 (10.7)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.0887	
NO	272	36 (13.2)	N.A. (N.A., N.A.)	258	5 (1.9)	N.A. (N.A., N.A.)	4.740 (1.810, 12.411) 0.0005	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	39 (13.0)	N.M.E.	284	5 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.0694
POSITIVE	229	36 (15.7)	N.A. (N.A., N.A.)	203	3 (1.5)	N.A. (N.A., N.A.)	7.973 (2.414, 26.332) <0.0001	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	2 (2.6)	N.A. (N.A., N.A.)	0.706 (0.064, 7.793) 0.7754	
NOT REPORTED	14	1 (7.1)	N.A. (7.69, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	32 (10.7)	N.A. (N.A., N.A.)	284	45 (15.8)	N.A. (N.A., N.A.)	0.416 (0.249, 0.695) 0.0006	
AGE CATEGORIZATION								0.3712
< 65	71	6 (8.5)	N.A. (N.A., N.A.)	87	10 (11.5)	N.A. (N.A., N.A.)	0.596 (0.207, 1.715) 0.3322	
>= 65 AND < 75	151	19 (12.6)	N.A. (N.A., N.A.)	123	18 (14.6)	N.A. (N.A., N.A.)	0.519 (0.251, 1.072) 0.0714	
>= 75	78	7 (9.0)	N.A. (23.52, N.A.)	74	17 (23.0)	N.A. (N.A., N.A.)	0.193 (0.065, 0.575) 0.0010	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.3798
MALE	232	24 (10.3)	N.A. (N.A., N.A.)	221	31 (14.0)	N.A. (N.A., N.A.)	0.469 (0.258, 0.853) 0.0111	
FEMALE	68	8 (11.8)	N.A. (23.52, N.A.)	63	14 (22.2)	N.A. (N.A., N.A.)	0.296 (0.107, 0.822) 0.0131	
RACE								0.6063
WHITE	263	29 (11.0)	N.A. (N.A., N.A.)	233	43 (18.5)	N.A. (N.A., N.A.)	0.382 (0.226, 0.647) 0.0002	
ASIAN	26	2 (7.7)	23.52 (N.A., N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	0.737 (0.067, 8.126) 0.8022	
OTHER	11	1 (9.1)	N.A. (10.18, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5229
NORTH AMERICA	32	3 (9.4)	N.A. (16.59, N.A.)	25	3 (12.0)	N.A. (N.A., N.A.)	0.463 (0.077, 2.775) 0.3878	
EUROPE	175	21 (12.0)	N.A. (N.A., N.A.)	164	35 (21.3)	N.A. (N.A., N.A.)	0.316 (0.169, 0.591) 0.0001	
ASIA	26	2 (7.7)	23.52 (N.A., N.A.)	38	2 (5.3)	N.A. (N.A., N.A.)	0.737 (0.067, 8.126) 0.8022	
REST OF WORLD	67	6 (9.0)	N.A. (N.A., N.A.)	57	5 (8.8)	N.A. (N.A., N.A.)	0.900 (0.260, 3.108) 0.8677	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.2133
0	113	8 (7.1)	N.A. (N.A., N.A.)	121	19 (15.7)	N.A. (N.A., N.A.)	0.218 (0.077, 0.618) 0.0018	
>= 1	187	24 (12.8)	N.A. (N.A., N.A.)	163	26 (16.0)	N.A. (N.A., N.A.)	0.535 (0.290, 0.984) 0.0410	
IVRS HISTOLOGY								0.6676
EPITHELIOID	233	27 (11.6)	N.A. (N.A., N.A.)	219	36 (16.4)	N.A. (N.A., N.A.)	0.422 (0.239, 0.746) 0.0022	
NON-EPITHELIOID	67	5 (7.5)	N.A. (N.A., N.A.)	65	9 (13.8)	N.A. (N.A., N.A.)	0.391 (0.120, 1.270) 0.1049	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.5629
STAGE I	12	2 (16.7)	N.A. (3.02, N.A.)	17	2 (11.8)	N.A. (N.A., N.A.)	1.408 (0.198, 10.026) 0.7311	
STAGE II	23	5 (21.7)	N.A. (16.59, N.A.)	21	5 (23.8)	N.A. (N.A., N.A.)	0.536 (0.128, 2.244) 0.3855	
STAGE III	102	16 (15.7)	N.A. (23.52, N.A.)	101	25 (24.8)	N.A. (N.A., N.A.)	0.345 (0.166, 0.719) 0.0029	
STAGE IV	158	9 (5.7)	N.A. (N.A., N.A.)	140	11 (7.9)	N.A. (N.A., N.A.)	0.479 (0.180, 1.275) 0.1324	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	2 (40.0)	N.A. (0.07, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.4140
NEVER	124	11 (8.9)	N.A. (N.A., N.A.)	116	24 (20.7)	N.A. (N.A., N.A.)	0.218 (0.090, 0.524) 0.0002	
FORMER	155	17 (11.0)	N.A. (N.A., N.A.)	153	20 (13.1)	N.A. (N.A., N.A.)	0.621 (0.310, 1.246) 0.1765	
CURRENT	18	4 (22.2)	N.A. (18.23, N.A.)	8	1 (12.5)	N.A. (0.03, N.A.)	0.610 (0.052, 7.137) 0.6914	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.3172
YES	28	6 (21.4)	20.24 (18.23, N.A.)	26	5 (19.2)	N.A. (N.A., N.A.)	0.516 (0.130, 2.044) 0.3386	
NO	272	26 (9.6)	N.A. (N.A., N.A.)	258	40 (15.5)	N.A. (N.A., N.A.)	0.401 (0.230, 0.698) 0.0008	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	32 (10.7)	N.M.E.	284	45 (15.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders

Adverse Events with SOC: Eye Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.4103
POSITIVE	229	26 (11.4)	N.A. (N.A., N.A.)	203	29 (14.3)	N.A. (N.A., N.A.)	0.456 (0.249, 0.836) 0.0093	
NEGATIVE	57	6 (10.5)	N.A. (N.A., N.A.)	76	16 (21.1)	N.A. (N.A., N.A.)	0.400 (0.146, 1.091) 0.0637	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	1 (0.3)	N.A. (N.A., N.A.)	284	19 (6.7)	N.A. (N.A., N.A.)	0.024 (0.002, 0.243) <0.0001	
AGE CATEGORIZATION								N.M.E.
< 65	71	1 (1.4)	N.M.E.	87	3 (3.4)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	0	N.M.E.	123	8 (6.5)	N.M.E.	N.M.E.	
>= 75	78	0	N.M.E.	74	8 (10.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9923
MALE	232	1 (0.4)	N.A. (N.A., N.A.)	221	15 (6.8)	N.A. (N.A., N.A.)	0.029 (0.003, 0.307) <0.0001	
FEMALE	68	0	N.A. (N.A., N.A.)	63	4 (6.3)	N.A. (N.A., N.A.)	N.M.E. 0.0351	
RACE								>0.9999
WHITE	263	1 (0.4)	N.A. (N.A., N.A.)	233	19 (8.2)	N.A. (N.A., N.A.)	0.024 (0.003, 0.229) <0.0001	
ASIAN	26	0	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	N.M.E. 0.2352	
EUROPE	175	1 (0.6)	N.A. (N.A., N.A.)	164	14 (8.5)	N.A. (N.A., N.A.)	0.035 (0.004, 0.331) <0.0001	
ASIA	26	0	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
REST OF WORLD	67	0	N.A. (N.A., N.A.)	57	4 (7.0)	N.A. (N.A., N.A.)	N.M.E. 0.0340	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9917
0	113	1 (0.9)	N.A. (N.A., N.A.)	121	8 (6.6)	N.A. (N.A., N.A.)	0.057 (0.005, 0.662) 0.0064	
>= 1	187	0	N.A. (N.A., N.A.)	163	11 (6.7)	N.A. (N.A., N.A.)	N.M.E. 0.0003	
IVRS HISTOLOGY								0.9941
EPITHELIOID	233	1 (0.4)	N.A. (N.A., N.A.)	219	18 (8.2)	N.A. (N.A., N.A.)	0.027 (0.003, 0.256) <0.0001	
NON-EPITHELIOID	67	0	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	N.M.E. 0.3211	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0665	
STAGE III	102	0	N.A. (N.A., N.A.)	101	12 (11.9)	N.A. (N.A., N.A.)	N.M.E. 0.0003	
STAGE IV	158	0	N.A. (N.A., N.A.)	140	4 (2.9)	N.A. (N.A., N.A.)	N.M.E. 0.0336	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	0	N.A. (N.A., N.A.)	116	7 (6.0)	N.A. (N.A., N.A.)	N.M.E. 0.0057	
FORMER	155	1 (0.6)	N.A. (N.A., N.A.)	153	11 (7.2)	N.A. (N.A., N.A.)	0.036 (0.003, 0.434) 0.0008	
CURRENT	18	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.03, N.A.)	N.M.E. 0.1336	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9931
YES	28	0	N.A. (N.A., N.A.)	26	3 (11.5)	N.A. (N.A., N.A.)	N.M.E. 0.0599	
NO	272	1 (0.4)	N.A. (N.A., N.A.)	258	16 (6.2)	N.A. (N.A., N.A.)	0.026 (0.002, 0.284) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	1 (0.3)	N.M.E.	284	19 (6.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Eye Disorders. PT: Lacrimation Increased

Adverse Events with SOC: Eye Disorders and PT: Lacrimation Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9930
POSITIVE	229	1 (0.4)	N.A. (N.A., N.A.)	203	12 (5.9)	N.A. (N.A., N.A.)	0.027 (0.002, 0.347) 0.0002	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	7 (9.2)	N.A. (N.A., N.A.)	N.M.E. 0.0215	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:40:16

Anhang 4-G 4.2.4.2: Subgruppenanalysen für Endpunkt UE Grad ≥ 3 auf SOC/PT-Ebene aus CA209-743

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	34 (11.3)	N.A. (N.A., N.A.)	284	10 (3.5)	N.A. (N.A., N.A.)	2.152 (1.019, 4.546) 0.0395	
AGE CATEGORIZATION								0.9949
< 65	71	4 (5.6)	N.A. (19.98, N.A.)	87	3 (3.4)	N.A. (N.A., N.A.)	0.836 (0.140, 5.005) 0.8444	
>= 65 AND < 75	151	19 (12.6)	N.A. (N.A., N.A.)	123	0	N.A. (N.A., N.A.)	N.M.E. 0.0019	
>= 75	78	11 (14.1)	N.A. (N.A., N.A.)	74	7 (9.5)	N.A. (N.A., N.A.)	1.183 (0.440, 3.177) 0.7429	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:18

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.2510
MALE	232	24 (10.3)	N.A. (N.A., N.A.)	221	9 (4.1)	N.A. (N.A., N.A.)	1.855 (0.827, 4.161) 0.1283	
FEMALE	68	10 (14.7)	N.A. (19.84, N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	4.739 (0.554, 40.558) 0.1169	
RACE								0.4135
WHITE	263	29 (11.0)	N.A. (N.A., N.A.)	233	6 (2.6)	N.A. (N.A., N.A.)	3.079 (1.236, 7.667) 0.0110	
ASIAN	26	4 (15.4)	N.A. (14.39, N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	0.743 (0.136, 4.062) 0.7309	
OTHER	11	1 (9.1)	N.A. (15.93, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:18

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.6590
NORTH AMERICA	32	5 (15.6)	N.A. (14.26, N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	2.233 (0.232, 21.476) 0.4775	
EUROPE	175	22 (12.6)	N.A. (N.A., N.A.)	164	5 (3.0)	N.A. (N.A., N.A.)	3.088 (1.131, 8.430) 0.0204	
ASIA	26	4 (15.4)	N.A. (14.39, N.A.)	38	4 (10.5)	N.A. (N.A., N.A.)	0.743 (0.136, 4.062) 0.7309	
REST OF WORLD	67	3 (4.5)	N.A. (19.84, N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. 0.3419	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.3935
0	113	10 (8.8)	N.A. (N.A., N.A.)	121	2 (1.7)	N.A. (N.A., N.A.)	3.277 (0.661, 16.235) 0.1235	
>= 1	187	24 (12.8)	N.A. (N.A., N.A.)	163	8 (4.9)	N.A. (N.A., N.A.)	1.814 (0.776, 4.242) 0.1633	
IVRS HISTOLOGY								0.2171
EPITHELIOID	233	27 (11.6)	N.A. (N.A., N.A.)	219	6 (2.7)	N.A. (N.A., N.A.)	2.573 (1.007, 6.577) 0.0406	
NON-EPITHELIOID	67	7 (10.4)	N.A. (N.A., N.A.)	65	4 (6.2)	N.A. (N.A., N.A.)	1.515 (0.427, 5.371) 0.5173	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.5253
STAGE I	12	1 (8.3)	N.A. (3.25, N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	1.649 (0.103, 26.376) 0.7208	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	0.909 (0.057, 14.529) 0.9461	
STAGE III	102	12 (11.8)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	6.197 (0.746, 51.465) 0.0532	
STAGE IV	158	20 (12.7)	N.A. (N.A., N.A.)	140	7 (5.0)	N.A. (N.A., N.A.)	1.836 (0.741, 4.550) 0.1829	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.5540
NEVER	124	15 (12.1)	N.A. (N.A., N.A.)	116	2 (1.7)	N.A. (N.A., N.A.)	3.978 (0.844, 18.736) 0.0590	
FORMER	155	17 (11.0)	N.A. (N.A., N.A.)	153	8 (5.2)	N.A. (N.A., N.A.)	1.520 (0.621, 3.720) 0.3561	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	1 (33.3)	N.A. (1.87, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9888
YES	28	3 (10.7)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.0982	
NO	272	31 (11.4)	N.A. (N.A., N.A.)	258	10 (3.9)	N.A. (N.A., N.A.)	1.866 (0.868, 4.014) 0.1048	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	34 (11.4)	N.M.E.	284	10 (3.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.8214
POSITIVE	229	22 (9.6)	N.A. (N.A., N.A.)	203	6 (3.0)	N.A. (N.A., N.A.)	2.098 (0.806, 5.460) 0.1204	
NEGATIVE	57	8 (14.0)	N.A. (15.21, N.A.)	76	3 (3.9)	N.A. (N.A., N.A.)	2.358 (0.563, 9.871) 0.2262	
NOT REPORTED	14	4 (28.6)	N.A. (4.60, N.A.)	5	1 (20.0)	N.A. (3.02, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:18

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	17 (5.7)	N.A. (N.A., N.A.)	284	1 (0.4)	N.A. (N.A., N.A.)	11.920 (1.550, 91.688) 0.0024	
AGE CATEGORIZATION								0.9999
< 65	71	2 (2.8)	N.A. (N.A., N.A.)	87	0	N.A. (N.A., N.A.)	N.M.E. 0.2628	
>= 65 AND < 75	151	11 (7.3)	N.A. (N.A., N.A.)	123	0	N.A. (N.A., N.A.)	N.M.E. 0.0083	
>= 75	78	4 (5.1)	N.A. (N.A., N.A.)	74	1 (1.4)	N.A. (N.A., N.A.)	2.897 (0.301, 27.888) 0.3356	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9907
MALE	232	13 (5.6)	N.A. (N.A., N.A.)	221	1 (0.5)	N.A. (N.A., N.A.)	9.078 (1.150, 71.675) 0.0110	
FEMALE	68	4 (5.9)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0952	
RACE								>0.9999
WHITE	263	14 (5.3)	N.A. (N.A., N.A.)	233	0	N.A. (N.A., N.A.)	N.M.E. 0.0013	
ASIAN	26	2 (7.7)	N.A. (14.39, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	1.481 (0.093, 23.673) 0.7800	
OTHER	11	1 (9.1)	N.A. (15.93, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								>0.9999
NORTH AMERICA	32	3 (9.4)	N.A. (15.21, N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.2215	
EUROPE	175	11 (6.3)	N.A. (N.A., N.A.)	164	0	N.A. (N.A., N.A.)	N.M.E. 0.0029	
ASIA	26	2 (7.7)	N.A. (14.39, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	1.481 (0.093, 23.673) 0.7800	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9912
0	113	7 (6.2)	N.A. (N.A., N.A.)	121	0	N.A. (N.A., N.A.)	N.M.E. 0.0188	
>= 1	187	10 (5.3)	N.A. (N.A., N.A.)	163	1 (0.6)	N.A. (N.A., N.A.)	6.468 (0.795, 52.618) 0.0445	
IVRS HISTOLOGY								0.9906
EPITHELIOID	233	13 (5.6)	N.A. (N.A., N.A.)	219	1 (0.5)	N.A. (N.A., N.A.)	8.761 (1.110, 69.175) 0.0129	
NON-EPITHELIOID	67	4 (6.0)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.0819	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	0.909 (0.057, 14.529) 0.9461	
STAGE III	102	6 (5.9)	N.A. (N.A., N.A.)	101	0	N.A. (N.A., N.A.)	N.M.E. 0.0415	
STAGE IV	158	10 (6.3)	N.A. (N.A., N.A.)	140	0	N.A. (N.A., N.A.)	N.M.E. 0.0102	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:18

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	6 (4.8)	N.A. (N.A., N.A.)	116	0	N.A. (N.A., N.A.)	N.M.E. 0.0805	
FORMER	155	9 (5.8)	N.A. (N.A., N.A.)	153	1 (0.7)	N.A. (N.A., N.A.)	7.260 (0.893, 59.032) 0.0299	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	1 (33.3)	N.A. (1.87, N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. 0.1573	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9917
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.3545	
NO	272	16 (5.9)	N.A. (N.A., N.A.)	258	1 (0.4)	N.A. (N.A., N.A.)	11.032 (1.424, 85.467) 0.0038	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	17 (5.7)	N.M.E.	284	1 (0.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Investigations. PT: Lipase Increased

Adverse Events with CTCAE Grade 3-4-5 with SOC: Investigations and PT: Lipase Increased Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9933
POSITIVE	229	10 (4.4)	N.A. (N.A., N.A.)	203	0	N.A. (N.A., N.A.)	N.M.E. 0.0108	
NEGATIVE	57	3 (5.3)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	2.675 (0.243, 29.501) 0.4031	
NOT REPORTED	14	4 (28.6)	N.A. (4.60, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	4 (1.3)	N.A. (N.A., N.A.)	284	13 (4.6)	N.A. (N.A., N.A.)	0.226 (0.066, 0.769) 0.0095	
AGE CATEGORIZATION								N.M.E.
< 65	71	2 (2.8)	N.M.E.	87	5 (5.7)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	0	N.M.E.	123	4 (3.3)	N.M.E.	N.M.E.	
>= 75	78	2 (2.6)	N.M.E.	74	4 (5.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9913
MALE	232	4 (1.7)	N.A. (N.A., N.A.)	221	10 (4.5)	N.A. (N.A., N.A.)	0.294 (0.083, 1.048) 0.0453	
FEMALE	68	0	N.A. (N.A., N.A.)	63	3 (4.8)	N.A. (N.A., N.A.)	N.M.E. 0.0687	
RACE								>0.9999
WHITE	263	4 (1.5)	N.A. (N.A., N.A.)	233	11 (4.7)	N.A. (N.A., N.A.)	0.249 (0.071, 0.865) 0.0184	
ASIAN	26	0	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
OTHER	11	0	N.A. (N.A., N.A.)	13	2 (15.4)	N.A. (4.57, N.A.)	N.M.E. 0.2004	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.9895
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	N.M.E. 0.2509	
EUROPE	175	3 (1.7)	N.A. (N.A., N.A.)	164	10 (6.1)	N.A. (N.A., N.A.)	0.274 (0.075, 0.997) 0.0353	
ASIA	26	0	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	2 (3.5)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.1462	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9894
0	113	0	N.A. (N.A., N.A.)	121	4 (3.3)	N.A. (N.A., N.A.)	N.M.E. 0.0519	
>= 1	187	4 (2.1)	N.A. (N.A., N.A.)	163	9 (5.5)	N.A. (N.A., N.A.)	0.296 (0.081, 1.078) 0.0503	
IVRS HISTOLOGY								0.9134
EPITHELIOID	233	3 (1.3)	N.A. (N.A., N.A.)	219	10 (4.6)	N.A. (N.A., N.A.)	0.199 (0.047, 0.851) 0.0166	
NON-EPITHELIOID	67	1 (1.5)	N.A. (N.A., N.A.)	65	3 (4.6)	N.A. (N.A., N.A.)	0.325 (0.034, 3.120) 0.3045	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	0	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	1 (4.3)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	2 (2.0)	N.M.E.	101	7 (6.9)	N.M.E.	N.M.E.	
STAGE IV	158	1 (0.6)	N.M.E.	140	6 (4.3)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	2 (1.6)	N.M.E.	116	5 (4.3)	N.M.E.	N.M.E.	
FORMER	155	1 (0.6)	N.M.E.	153	7 (4.6)	N.M.E.	N.M.E.	
CURRENT	18	1 (5.6)	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.7619
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	4 (15.4)	N.A. (N.A., N.A.)	0.218 (0.024, 1.948) 0.1337	
NO	272	3 (1.1)	N.A. (N.A., N.A.)	258	9 (3.5)	N.A. (N.A., N.A.)	0.221 (0.050, 0.981) 0.0303	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	4 (1.3)	N.M.E.	284	13 (4.6)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: General Disorders and Administration Site Conditions and PT: Asthenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9891
POSITIVE	229	4 (1.7)	N.A. (N.A., N.A.)	203	6 (3.0)	N.A. (N.A., N.A.)	0.454 (0.115, 1.789) 0.2471	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	7 (9.2)	N.A. (N.A., N.A.)	N.M.E. 0.0238	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	21 (7.0)	N.A. (N.A., N.A.)	284	86 (30.3)	N.A. (N.A., N.A.)	0.136 (0.078, 0.239) <0.0001	
AGE CATEGORIZATION								0.1376
< 65	71	6 (8.5)	N.A. (N.A., N.A.)	87	18 (20.7)	N.A. (N.A., N.A.)	0.330 (0.123, 0.889) 0.0211	
>= 65 AND < 75	151	7 (4.6)	N.A. (N.A., N.A.)	123	38 (30.9)	N.A. (N.A., N.A.)	0.041 (0.011, 0.151) <0.0001	
>= 75	78	8 (10.3)	N.A. (N.A., N.A.)	74	30 (40.5)	N.A. (3.61, N.A.)	0.177 (0.078, 0.402) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9637
MALE	232	15 (6.5)	N.A. (N.A., N.A.)	221	64 (29.0)	N.A. (N.A., N.A.)	0.120 (0.061, 0.238) <0.0001	
FEMALE	68	6 (8.8)	N.A. (N.A., N.A.)	63	22 (34.9)	N.A. (3.94, N.A.)	0.183 (0.069, 0.485) 0.0001	
RACE								0.0547
WHITE	263	14 (5.3)	N.A. (N.A., N.A.)	233	65 (27.9)	N.A. (N.A., N.A.)	0.121 (0.062, 0.235) <0.0001	
ASIAN	26	7 (26.9)	17.74 (7.39, N.A.)	38	15 (39.5)	N.A. (3.42, N.A.)	0.345 (0.114, 1.040) 0.0477	
OTHER	11	0	N.A. (N.A., N.A.)	13	6 (46.2)	N.A. (0.49, N.A.)	N.M.E. 0.0106	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.0398**
NORTH AMERICA	32	2 (6.3)	N.A. (N.A., N.A.)	25	5 (20.0)	N.A. (N.A., N.A.)	0.292 (0.057, 1.505) 0.1173	
EUROPE	175	8 (4.6)	N.A. (N.A., N.A.)	164	54 (32.9)	N.A. (N.A., N.A.)	0.103 (0.047, 0.227) <0.0001	
ASIA	26	7 (26.9)	17.74 (7.39, N.A.)	38	15 (39.5)	N.A. (3.42, N.A.)	0.345 (0.114, 1.040) 0.0477	
REST OF WORLD	67	4 (6.0)	N.A. (N.A., N.A.)	57	12 (21.1)	N.A. (N.A., N.A.)	0.068 (0.009, 0.522) 0.0006	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.4754
0	113	7 (6.2)	N.A. (N.A., N.A.)	121	39 (32.2)	N.A. (N.A., N.A.)	0.072 (0.024, 0.222) <0.0001	
>= 1	187	14 (7.5)	N.A. (N.A., N.A.)	163	47 (28.8)	N.A. (N.A., N.A.)	0.184 (0.096, 0.355) <0.0001	
IVRS HISTOLOGY								0.9619
EPITHELIOID	233	15 (6.4)	N.A. (N.A., N.A.)	219	62 (28.3)	N.A. (N.A., N.A.)	0.137 (0.071, 0.265) <0.0001	
NON-EPITHELIOID	67	6 (9.0)	N.A. (N.A., N.A.)	65	24 (36.9)	N.A. (3.61, N.A.)	0.135 (0.047, 0.391) <0.0001	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9735
STAGE I	12	0	N.A. (N.A., N.A.)	17	2 (11.8)	N.A. (N.A., N.A.)	N.M.E. 0.2605	
STAGE II	23	0	N.A. (N.A., N.A.)	21	7 (33.3)	N.A. (4.17, N.A.)	N.M.E. 0.0041	
STAGE III	102	8 (7.8)	N.A. (N.A., N.A.)	101	32 (31.7)	N.A. (N.A., N.A.)	0.103 (0.037, 0.293) <0.0001	
STAGE IV	158	13 (8.2)	N.A. (N.A., N.A.)	140	44 (31.4)	N.A. (N.A., N.A.)	0.181 (0.092, 0.357) <0.0001	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (0.66, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.8934
NEVER	124	10 (8.1)	N.A. (N.A., N.A.)	116	33 (28.4)	N.A. (N.A., N.A.)	0.205 (0.094, 0.443) <0.0001	
FORMER	155	10 (6.5)	N.A. (N.A., N.A.)	153	50 (32.7)	N.A. (N.A., N.A.)	0.089 (0.037, 0.215) <0.0001	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	2 (25.0)	N.A. (0.23, N.A.)	0.193 (0.017, 2.133) 0.1342	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (0.26, N.A.)	N.M.E. 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.4188
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	8 (30.8)	N.A. (2.76, N.A.)	0.094 (0.012, 0.752) 0.0054	
NO	272	20 (7.4)	N.A. (N.A., N.A.)	258	78 (30.2)	N.A. (N.A., N.A.)	0.141 (0.079, 0.253) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	21 (7.0)	N.M.E.	284	86 (30.3)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.3523
POSITIVE	229	16 (7.0)	N.A. (N.A., N.A.)	203	66 (32.5)	N.A. (N.A., N.A.)	0.116 (0.060, 0.224) <0.0001	
NEGATIVE	57	5 (8.8)	N.A. (N.A., N.A.)	76	20 (26.3)	N.A. (N.A., N.A.)	0.251 (0.086, 0.733) 0.0063	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	10 (3.3)	N.A. (N.A., N.A.)	284	39 (13.7)	N.A. (N.A., N.A.)	0.172 (0.079, 0.374) <0.0001	
AGE CATEGORIZATION								0.2683
< 65	71	4 (5.6)	N.A. (N.A., N.A.)	87	10 (11.5)	N.A. (N.A., N.A.)	0.368 (0.101, 1.336) 0.1133	
>= 65 AND < 75	151	2 (1.3)	N.A. (N.A., N.A.)	123	14 (11.4)	N.A. (N.A., N.A.)	0.035 (0.004, 0.312) <0.0001	
>= 75	78	4 (5.1)	N.A. (N.A., N.A.)	74	15 (20.3)	N.A. (N.A., N.A.)	0.227 (0.075, 0.683) 0.0039	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5640
MALE	232	6 (2.6)	N.A. (N.A., N.A.)	221	28 (12.7)	N.A. (N.A., N.A.)	0.114 (0.038, 0.335) <0.0001	
FEMALE	68	4 (5.9)	N.A. (N.A., N.A.)	63	11 (17.5)	N.A. (N.A., N.A.)	0.320 (0.102, 1.006) 0.0399	
RACE								0.1181
WHITE	263	5 (1.9)	N.A. (N.A., N.A.)	233	26 (11.2)	N.A. (N.A., N.A.)	0.133 (0.046, 0.382) <0.0001	
ASIAN	26	5 (19.2)	N.A. (7.39, N.A.)	38	9 (23.7)	N.A. (N.A., N.A.)	0.528 (0.156, 1.789) 0.2977	
OTHER	11	0	N.A. (N.A., N.A.)	13	4 (30.8)	N.A. (2.50, N.A.)	N.M.E. 0.0532	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.1513
NORTH AMERICA	32	1 (3.1)	N.A. (N.A., N.A.)	25	3 (12.0)	N.A. (N.A., N.A.)	0.252 (0.026, 2.426) 0.1974	
EUROPE	175	3 (1.7)	N.A. (N.A., N.A.)	164	21 (12.8)	N.A. (N.A., N.A.)	0.128 (0.038, 0.428) <0.0001	
ASIA	26	5 (19.2)	N.A. (7.39, N.A.)	38	9 (23.7)	N.A. (N.A., N.A.)	0.528 (0.156, 1.789) 0.2977	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	6 (10.5)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0090	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.4703
0	113	4 (3.5)	N.A. (N.A., N.A.)	121	13 (10.7)	N.A. (N.A., N.A.)	0.193 (0.052, 0.721) 0.0071	
>= 1	187	6 (3.2)	N.A. (N.A., N.A.)	163	26 (16.0)	N.A. (N.A., N.A.)	0.160 (0.061, 0.416) <0.0001	
IVRS HISTOLOGY								0.5681
EPITHELIOID	233	7 (3.0)	N.A. (N.A., N.A.)	219	24 (11.0)	N.A. (N.A., N.A.)	0.207 (0.082, 0.518) 0.0002	
NON-EPITHELIOID	67	3 (4.5)	N.A. (N.A., N.A.)	65	15 (23.1)	N.A. (N.A., N.A.)	0.115 (0.026, 0.502) 0.0005	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:18

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.8212
STAGE I	12	0	N.A. (N.A., N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	N.M.E. 0.4669	
STAGE II	23	0	N.A. (N.A., N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	N.M.E. 0.0757	
STAGE III	102	5 (4.9)	N.A. (N.A., N.A.)	101	12 (11.9)	N.A. (N.A., N.A.)	0.237 (0.067, 0.840) 0.0152	
STAGE IV	158	5 (3.2)	N.A. (N.A., N.A.)	140	23 (16.4)	N.A. (N.A., N.A.)	0.155 (0.056, 0.427) <0.0001	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.1621
NEVER	124	7 (5.6)	N.A. (N.A., N.A.)	116	11 (9.5)	N.A. (N.A., N.A.)	0.514 (0.190, 1.390) 0.1823	
FORMER	155	3 (1.9)	N.A. (N.A., N.A.)	153	27 (17.6)	N.A. (N.A., N.A.)	0.055 (0.012, 0.244) <0.0001	
CURRENT	18	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.23, N.A.)	N.M.E. 0.1336	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.8575
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	3 (11.5)	N.A. (N.A., N.A.)	0.293 (0.030, 2.816) 0.2579	
NO	272	9 (3.3)	N.A. (N.A., N.A.)	258	36 (14.0)	N.A. (N.A., N.A.)	0.162 (0.071, 0.371) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	10 (3.3)	N.M.E.	284	39 (13.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Anaemia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.8369
POSITIVE	229	8 (3.5)	N.A. (N.A., N.A.)	203	29 (14.3)	N.A. (N.A., N.A.)	0.153 (0.061, 0.379) <0.0001	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	10 (13.2)	N.A. (N.A., N.A.)	0.273 (0.060, 1.244) 0.0721	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	4 (1.3)	N.A. (N.A., N.A.)	284	45 (15.8)	N.A. (N.A., N.A.)	0.039 (0.009, 0.160) <0.0001	
AGE CATEGORIZATION								0.7698
< 65	71	0	N.A. (N.A., N.A.)	87	8 (9.2)	N.A. (N.A., N.A.)	N.M.E. 0.0090	
>= 65 AND < 75	151	2 (1.3)	N.A. (N.A., N.A.)	123	22 (17.9)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) <0.0001	
>= 75	78	2 (2.6)	N.A. (N.A., N.A.)	74	15 (20.3)	N.A. (N.A., N.A.)	0.114 (0.026, 0.499) 0.0005	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9318
MALE	232	3 (1.3)	N.A. (N.A., N.A.)	221	36 (16.3)	N.A. (N.A., N.A.)	0.024 (0.003, 0.178) <0.0001	
FEMALE	68	1 (1.5)	N.A. (N.A., N.A.)	63	9 (14.3)	N.A. (N.A., N.A.)	0.095 (0.012, 0.752) 0.0054	
RACE								0.7187
WHITE	263	3 (1.1)	N.A. (N.A., N.A.)	233	33 (14.2)	N.A. (N.A., N.A.)	0.050 (0.012, 0.208) <0.0001	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	7 (18.4)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0262	
OTHER	11	0	N.A. (N.A., N.A.)	13	5 (38.5)	N.A. (0.49, N.A.)	N.M.E. 0.0218	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.6872
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	1 (4.0)	N.A. (N.A., N.A.)	N.M.E. 0.2579	
EUROPE	175	2 (1.1)	N.A. (N.A., N.A.)	164	32 (19.5)	N.A. (N.A., N.A.)	0.052 (0.012, 0.217) <0.0001	
ASIA	26	1 (3.8)	N.A. (N.A., N.A.)	38	7 (18.4)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0262	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	5 (8.8)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0166	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.3896
0	113	1 (0.9)	N.A. (N.A., N.A.)	121	23 (19.0)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) <0.0001	
>= 1	187	3 (1.6)	N.A. (N.A., N.A.)	163	22 (13.5)	N.A. (N.A., N.A.)	0.075 (0.018, 0.318) <0.0001	
IVRS HISTOLOGY								0.8450
EPITHELIOID	233	3 (1.3)	N.A. (N.A., N.A.)	219	35 (16.0)	N.A. (N.A., N.A.)	0.050 (0.012, 0.206) <0.0001	
NON-EPITHELIOID	67	1 (1.5)	N.A. (N.A., N.A.)	65	10 (15.4)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0010	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9874
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	0	N.A. (N.A., N.A.)	21	3 (14.3)	N.A. (N.A., N.A.)	N.M.E. 0.0718	
STAGE III	102	2 (2.0)	N.A. (N.A., N.A.)	101	23 (22.8)	N.A. (N.A., N.A.)	0.038 (0.005, 0.283) <0.0001	
STAGE IV	158	2 (1.3)	N.A. (N.A., N.A.)	140	18 (12.9)	N.A. (N.A., N.A.)	0.046 (0.006, 0.348) <0.0001	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (0.66, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9999
NEVER	124	2 (1.6)	N.A. (N.A., N.A.)	116	20 (17.2)	N.A. (N.A., N.A.)	0.043 (0.006, 0.319) <0.0001	
FORMER	155	2 (1.3)	N.A. (N.A., N.A.)	153	23 (15.0)	N.A. (N.A., N.A.)	0.040 (0.005, 0.300) <0.0001	
CURRENT	18	0	N.A. (N.A., N.A.)	8	1 (12.5)	N.A. (0.49, N.A.)	N.M.E. 0.1336	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (0.26, N.A.)	N.M.E. 0.4795	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.5894
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	6 (23.1)	N.A. (N.A., N.A.)	0.129 (0.016, 1.074) 0.0250	
NO	272	3 (1.1)	N.A. (N.A., N.A.)	258	39 (15.1)	N.A. (N.A., N.A.)	0.023 (0.003, 0.165) <0.0001	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	4 (1.3)	N.M.E.	284	45 (15.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Neutropenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.7639
POSITIVE	229	3 (1.3)	N.A. (N.A., N.A.)	203	33 (16.3)	N.A. (N.A., N.A.)	0.024 (0.003, 0.179) <0.0001	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	12 (15.8)	N.A. (N.A., N.A.)	0.105 (0.014, 0.808) 0.0080	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	4 (1.3)	N.A. (N.A., N.A.)	284	11 (3.9)	N.A. (N.A., N.A.)	0.193 (0.047, 0.783) 0.0113	
AGE CATEGORIZATION								N.M.E.
< 65	71	1 (1.4)	N.M.E.	87	1 (1.1)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	1 (0.7)	N.M.E.	123	4 (3.3)	N.M.E.	N.M.E.	
>= 75	78	2 (2.6)	N.M.E.	74	6 (8.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.8620
MALE	232	3 (1.3)	N.A. (N.A., N.A.)	221	9 (4.1)	N.A. (N.A., N.A.)	0.215 (0.046, 0.995) 0.0303	
FEMALE	68	1 (1.5)	N.A. (N.A., N.A.)	63	2 (3.2)	N.A. (N.A., N.A.)	0.136 (0.007, 2.816) 0.1741	
RACE								0.6965
WHITE	263	3 (1.1)	N.A. (N.A., N.A.)	233	7 (3.0)	N.A. (N.A., N.A.)	0.257 (0.053, 1.240) 0.0680	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.4206	
OTHER	11	0	N.A. (N.A., N.A.)	13	3 (23.1)	N.A. (2.50, N.A.)	N.M.E. 0.0979	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.5924
NORTH AMERICA	32	0	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
EUROPE	175	2 (1.1)	N.A. (N.A., N.A.)	164	9 (5.5)	N.A. (N.A., N.A.)	0.103 (0.013, 0.815) 0.0081	
ASIA	26	1 (3.8)	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.4206	
REST OF WORLD	67	1 (1.5)	N.A. (N.A., N.A.)	57	1 (1.8)	N.A. (N.A., N.A.)	0.923 (0.058, 14.762) 0.9548	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	1 (0.9)	N.M.E.	121	6 (5.0)	N.M.E.	N.M.E.	
>= 1	187	3 (1.6)	N.M.E.	163	5 (3.1)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								0.9534
EPITHELIOID	233	3 (1.3)	N.A. (N.A., N.A.)	219	8 (3.7)	N.A. (N.A., N.A.)	0.238 (0.051, 1.123) 0.0486	
NON-EPITHELIOID	67	1 (1.5)	N.A. (N.A., N.A.)	65	3 (4.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0815	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	0	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	0	N.M.E.	21	1 (4.8)	N.M.E.	N.M.E.	
STAGE III	102	1 (1.0)	N.M.E.	101	7 (6.9)	N.M.E.	N.M.E.	
STAGE IV	158	3 (1.9)	N.M.E.	140	3 (2.1)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	1 (0.8)	N.M.E.	116	4 (3.4)	N.M.E.	N.M.E.	
FORMER	155	2 (1.3)	N.M.E.	153	6 (3.9)	N.M.E.	N.M.E.	
CURRENT	18	1 (5.6)	N.M.E.	8	1 (12.5)	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9997
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	4 (1.5)	N.A. (N.A., N.A.)	258	11 (4.3)	N.A. (N.A., N.A.)	0.193 (0.047, 0.786) 0.0115	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	4 (1.3)	N.M.E.	284	11 (3.9)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Adverse Events with CTCAE Grade 3-4-5 with SOC: Blood and Lymphatic System Disorders and PT: Thrombocytopenia Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.5431
POSITIVE	229	3 (1.3)	N.A. (N.A., N.A.)	203	9 (4.4)	N.A. (N.A., N.A.)	0.197 (0.043, 0.912) 0.0207	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	2 (2.6)	N.A. (N.A., N.A.)	0.282 (0.018, 4.481) 0.3583	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	20 (6.7)	N.A. (N.A., N.A.)	284	0	N.A. (N.A., N.A.)	N.M.E. 0.0004	
AGE CATEGORIZATION								>0.9999
< 65	71	6 (8.5)	N.A. (N.A., N.A.)	87	0	N.A. (N.A., N.A.)	N.M.E. 0.0125	
>= 65 AND < 75	151	10 (6.6)	N.A. (N.A., N.A.)	123	0	N.A. (N.A., N.A.)	N.M.E. 0.0405	
>= 75	78	4 (5.1)	N.A. (N.A., N.A.)	74	0	N.A. (N.A., N.A.)	N.M.E. 0.0938	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								>0.9999
MALE	232	15 (6.5)	N.A. (N.A., N.A.)	221	0	N.A. (N.A., N.A.)	N.M.E. 0.0031	
FEMALE	68	5 (7.4)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0511	
RACE								>0.9999
WHITE	263	14 (5.3)	N.A. (N.A., N.A.)	233	0	N.A. (N.A., N.A.)	N.M.E. 0.0026	
ASIAN	26	5 (19.2)	22.11 (15.93, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0329	
OTHER	11	1 (9.1)	N.A. (16.56, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:18

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	1 (3.1)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	8 (4.6)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	5 (19.2)	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	6 (9.0)	N.M.E.	57	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								>0.9999
0	113	9 (8.0)	N.A. (N.A., N.A.)	121	0	N.A. (N.A., N.A.)	N.M.E. 0.0058	
>= 1	187	11 (5.9)	N.A. (N.A., N.A.)	163	0	N.A. (N.A., N.A.)	N.M.E. 0.0196	
IVRS HISTOLOGY								0.9999
EPITHELIOID	233	13 (5.6)	N.A. (N.A., N.A.)	219	0	N.A. (N.A., N.A.)	N.M.E. 0.0031	
NON-EPITHELIOID	67	7 (10.4)	N.A. (22.11, N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.0434	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Nivo + Ipi vs. Chemo Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	2 (16.7)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	1 (4.3)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	8 (7.8)	N.M.E.	101	0	N.M.E.	N.M.E.	
STAGE IV	158	9 (5.7)	N.M.E.	140	0	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	7 (5.6)	N.A. (N.A., N.A.)	116	0	N.A. (N.A., N.A.)	N.M.E. 0.0882	
FORMER	155	12 (7.7)	N.A. (N.A., N.A.)	153	0	N.A. (N.A., N.A.)	N.M.E. 0.0023	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9999
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.3384	
NO	272	19 (7.0)	N.A. (N.A., N.A.)	258	0	N.A. (N.A., N.A.)	N.M.E. 0.0006	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	20 (6.7)	N.M.E.	284	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9998
POSITIVE	229	17 (7.4)	N.A. (N.A., N.A.)	203	0	N.A. (N.A., N.A.)	N.M.E. 0.0010	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.2284	
NOT REPORTED	14	1 (7.1)	N.A. (7.69, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	15 (5.0)	N.A. (N.A., N.A.)	284	3 (1.1)	N.A. (N.A., N.A.)	3.554 (0.991, 12.743) 0.0375	
AGE CATEGORIZATION								N.M.E.
< 65	71	2 (2.8)	N.M.E.	87	2 (2.3)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	6 (4.0)	N.M.E.	123	1 (0.8)	N.M.E.	N.M.E.	
>= 75	78	7 (9.0)	N.M.E.	74	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.1696
MALE	232	11 (4.7)	N.A. (N.A., N.A.)	221	1 (0.5)	N.A. (N.A., N.A.)	9.866 (1.263, 77.085) 0.0071	
FEMALE	68	4 (5.9)	N.A. (N.A., N.A.)	63	2 (3.2)	N.A. (N.A., N.A.)	0.456 (0.041, 5.035) 0.5103	
RACE								>0.9999
WHITE	263	13 (4.9)	N.A. (N.A., N.A.)	233	3 (1.3)	N.A. (N.A., N.A.)	2.717 (0.735, 10.037) 0.1183	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.2272	
OTHER	11	1 (9.1)	N.A. (3.22, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.2733	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	3 (9.4)	N.M.E.	25	1 (4.0)	N.M.E.	N.M.E.	
EUROPE	175	6 (3.4)	N.M.E.	164	1 (0.6)	N.M.E.	N.M.E.	
ASIA	26	1 (3.8)	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	5 (7.5)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.5466
0	113	7 (6.2)	N.A. (N.A., N.A.)	121	1 (0.8)	N.A. (N.A., N.A.)	6.427 (0.774, 53.368) 0.0473	
>= 1	187	8 (4.3)	N.A. (N.A., N.A.)	163	2 (1.2)	N.A. (N.A., N.A.)	2.279 (0.442, 11.760) 0.3115	
IVRS HISTOLOGY								0.4173
EPITHELIOID	233	13 (5.6)	N.A. (N.A., N.A.)	219	2 (0.9)	N.A. (N.A., N.A.)	4.295 (0.928, 19.880) 0.0420	
NON-EPITHELIOID	67	2 (3.0)	N.A. (N.A., N.A.)	65	1 (1.5)	N.A. (N.A., N.A.)	2.081 (0.188, 22.973) 0.5409	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9927
STAGE I	12	0	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.3393	
STAGE III	102	6 (5.9)	N.A. (N.A., N.A.)	101	1 (1.0)	N.A. (N.A., N.A.)	5.200 (0.607, 44.521) 0.0927	
STAGE IV	158	8 (5.1)	N.A. (N.A., N.A.)	140	2 (1.4)	N.A. (N.A., N.A.)	2.245 (0.435, 11.578) 0.3207	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	4 (3.2)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	1.873 (0.170, 20.656) 0.6024	
FORMER	155	8 (5.2)	N.A. (N.A., N.A.)	153	2 (1.3)	N.A. (N.A., N.A.)	3.609 (0.749, 17.380) 0.0868	
CURRENT	18	3 (16.7)	N.A. (10.61, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.3634	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9932
YES	28	1 (3.6)	N.A. (16.16, N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	14 (5.1)	N.A. (N.A., N.A.)	258	3 (1.2)	N.A. (N.A., N.A.)	3.579 (0.998, 12.831) 0.0364	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	15 (5.0)	N.M.E.	284	3 (1.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9926
POSITIVE	229	11 (4.8)	N.A. (N.A., N.A.)	203	3 (1.5)	N.A. (N.A., N.A.)	2.690 (0.728, 9.939) 0.1222	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.2482	
NOT REPORTED	14	3 (21.4)	N.A. (13.31, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	14 (4.7)	N.A. (N.A., N.A.)	284	1 (0.4)	N.A. (N.A., N.A.)	8.658 (1.097, 68.341) 0.0135	
AGE CATEGORIZATION								N.M.E.
< 65	71	4 (5.6)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	6 (4.0)	N.M.E.	123	0	N.M.E.	N.M.E.	
>= 75	78	4 (5.1)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9885
MALE	232	13 (5.6)	N.A. (N.A., N.A.)	221	0	N.A. (N.A., N.A.)	N.M.E. 0.0030	
FEMALE	68	1 (1.5)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.3024	
RACE								>0.9999
WHITE	263	10 (3.8)	N.A. (N.A., N.A.)	233	1 (0.4)	N.A. (N.A., N.A.)	6.265 (0.771, 50.929) 0.0491	
ASIAN	26	3 (11.5)	23.33 (23.33, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0842	
OTHER	11	1 (9.1)	N.A. (8.94, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	0	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	8 (4.6)	N.M.E.	164	1 (0.6)	N.M.E.	N.M.E.	
ASIA	26	3 (11.5)	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	3 (4.5)	N.M.E.	57	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9908
0	113	4 (3.5)	N.A. (N.A., N.A.)	121	1 (0.8)	N.A. (N.A., N.A.)	3.202 (0.333, 30.786) 0.2860	
>= 1	187	10 (5.3)	N.A. (N.A., N.A.)	163	0	N.A. (N.A., N.A.)	N.M.E. 0.0220	
IVRS HISTOLOGY								0.9915
EPITHELIOID	233	11 (4.7)	N.A. (N.A., N.A.)	219	1 (0.5)	N.A. (N.A., N.A.)	7.646 (0.956, 61.140) 0.0235	
NON-EPITHELIOID	67	3 (4.5)	N.A. (23.33, N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.3210	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	1 (8.3)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	2 (8.7)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	6 (5.9)	N.M.E.	101	1 (1.0)	N.M.E.	N.M.E.	
STAGE IV	158	4 (2.5)	N.M.E.	140	0	N.M.E.	N.M.E.	
NOT REPORTED	5	1 (20.0)	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	2 (1.6)	N.A. (N.A., N.A.)	116	1 (0.9)	N.A. (N.A., N.A.)	0.923 (0.058, 14.761) 0.9550	
FORMER	155	11 (7.1)	N.A. (N.A., N.A.)	153	0	N.A. (N.A., N.A.)	N.M.E. 0.0072	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.7150	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9996
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	14 (5.1)	N.A. (N.A., N.A.)	258	1 (0.4)	N.A. (N.A., N.A.)	8.715 (1.104, 68.795) 0.0132	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	14 (4.7)	N.M.E.	284	1 (0.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Skin and Subcutaneous Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9931
POSITIVE	229	11 (4.8)	N.A. (N.A., N.A.)	203	0	N.A. (N.A., N.A.)	N.M.E. 0.0073	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	1 (1.3)	N.A. (N.A., N.A.)	1.364 (0.085, 21.818) 0.8254	
NOT REPORTED	14	1 (7.1)	N.A. (10.38, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	13 (4.3)	N.A. (N.A., N.A.)	284	2 (0.7)	N.A. (N.A., N.A.)	4.430 (0.960, 20.447) 0.0370	
AGE CATEGORIZATION								N.M.E.
< 65	71	3 (4.2)	N.M.E.	87	1 (1.1)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	7 (4.6)	N.M.E.	123	0	N.M.E.	N.M.E.	
>= 75	78	3 (3.8)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9908
MALE	232	11 (4.7)	N.A. (N.A., N.A.)	221	2 (0.9)	N.A. (N.A., N.A.)	3.983 (0.849, 18.689) 0.0585	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.3343	
RACE								0.5746
WHITE	263	11 (4.2)	N.A. (N.A., N.A.)	233	1 (0.4)	N.A. (N.A., N.A.)	7.342 (0.920, 58.574) 0.0275	
ASIAN	26	1 (3.8)	N.A. (12.45, N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.4173	
OTHER	11	1 (9.1)	N.A. (1.38, N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. 0.2733	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:18

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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	1 (3.1)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	6 (3.4)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	1 (3.8)	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
REST OF WORLD	67	5 (7.5)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	7 (6.2)	N.M.E.	121	0	N.M.E.	N.M.E.	
>= 1	187	6 (3.2)	N.M.E.	163	2 (1.2)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								N.M.E.
EPITHELIOID	233	7 (3.0)	N.M.E.	219	1 (0.5)	N.M.E.	N.M.E.	
NON-EPITHELIOID	67	6 (9.0)	N.M.E.	65	1 (1.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	1 (8.3)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	4 (17.4)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	6 (5.9)	N.M.E.	101	1 (1.0)	N.M.E.	N.M.E.	
STAGE IV	158	2 (1.3)	N.M.E.	140	1 (0.7)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	7 (5.6)	N.M.E.	116	0	N.M.E.	N.M.E.	
FORMER	155	5 (3.2)	N.M.E.	153	2 (1.3)	N.M.E.	N.M.E.	
CURRENT	18	0	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	1 (33.3)	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9997
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	13 (4.8)	N.A. (N.A., N.A.)	258	2 (0.8)	N.A. (N.A., N.A.)	4.468 (0.968, 20.623) 0.0358	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	13 (4.3)	N.M.E.	284	2 (0.7)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Adverse Events with CTCAE Grade 3-4-5
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Adverse Events with CTCAE Grade 3-4-5 with SOC: Musculoskeletal and Connective Tissue Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9930
POSITIVE	229	8 (3.5)	N.A. (N.A., N.A.)	203	2 (1.0)	N.A. (N.A., N.A.)	2.740 (0.556, 13.500) 0.1969	
NEGATIVE	57	4 (7.0)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.0994	
NOT REPORTED	14	1 (7.1)	N.A. (6.51, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Anhang 4-G 4.2.4.3: Subgruppenanalysen für Endpunkt schwerwiegende UE auf SOC/PT-Ebene aus CA209-743

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	43 (14.3)	N.A. (N.A., N.A.)	284	20 (7.0)	N.A. (N.A., N.A.)	1.732 (1.000, 3.001) 0.0472	
AGE CATEGORIZATION								0.6922
< 65	71	11 (15.5)	N.A. (N.A., N.A.)	87	7 (8.0)	N.A. (N.A., N.A.)	1.646 (0.613, 4.421) 0.3180	
>= 65 AND < 75	151	17 (11.3)	N.A. (N.A., N.A.)	123	8 (6.5)	N.A. (N.A., N.A.)	1.482 (0.622, 3.534) 0.3714	
>= 75	78	15 (19.2)	N.A. (19.09, N.A.)	74	5 (6.8)	N.A. (N.A., N.A.)	2.418 (0.851, 6.867) 0.0871	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.0228**
MALE	232	38 (16.4)	N.A. (N.A., N.A.)	221	13 (5.9)	N.A. (N.A., N.A.)	2.415 (1.263, 4.615) 0.0059	
FEMALE	68	5 (7.4)	N.A. (N.A., N.A.)	63	7 (11.1)	N.A. (N.A., N.A.)	0.525 (0.154, 1.794) 0.2951	
RACE								0.4743
WHITE	263	40 (15.2)	N.A. (N.A., N.A.)	233	15 (6.4)	N.A. (N.A., N.A.)	1.964 (1.064, 3.628) 0.0279	
ASIAN	26	3 (11.5)	N.A. (N.A., N.A.)	38	5 (13.2)	N.A. (N.A., N.A.)	1.010 (0.241, 4.232) 0.9896	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.1956
NORTH AMERICA	32	2 (6.3)	N.A. (22.24, N.A.)	25	3 (12.0)	N.A. (N.A., N.A.)	0.270 (0.028, 2.601) 0.2244	
EUROPE	175	27 (15.4)	N.A. (N.A., N.A.)	164	9 (5.5)	N.A. (N.A., N.A.)	2.360 (1.087, 5.126) 0.0252	
ASIA	26	3 (11.5)	N.A. (N.A., N.A.)	38	5 (13.2)	N.A. (N.A., N.A.)	1.010 (0.241, 4.232) 0.9896	
REST OF WORLD	67	11 (16.4)	N.A. (N.A., N.A.)	57	3 (5.3)	N.A. (N.A., N.A.)	2.742 (0.742, 10.136) 0.1144	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.2883
0	113	17 (15.0)	N.A. (22.24, N.A.)	121	6 (5.0)	N.A. (N.A., N.A.)	2.015 (0.745, 5.451) 0.1586	
>= 1	187	26 (13.9)	N.A. (N.A., N.A.)	163	14 (8.6)	N.A. (N.A., N.A.)	1.568 (0.811, 3.033) 0.1773	
IVRS HISTOLOGY								0.4242
EPITHELIOID	233	34 (14.6)	N.A. (N.A., N.A.)	219	14 (6.4)	N.A. (N.A., N.A.)	1.894 (0.993, 3.613) 0.0486	
NON-EPITHELIOID	67	9 (13.4)	N.A. (N.A., N.A.)	65	6 (9.2)	N.A. (N.A., N.A.)	1.333 (0.462, 3.843) 0.5934	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.4587
STAGE I	12	1 (8.3)	N.A. (N.A., N.A.)	17	2 (11.8)	N.A. (N.A., N.A.)	0.798 (0.072, 8.859) 0.8541	
STAGE II	23	4 (17.4)	N.A. (N.A., N.A.)	21	1 (4.8)	N.A. (N.A., N.A.)	4.089 (0.456, 36.628) 0.1722	
STAGE III	102	17 (16.7)	N.A. (N.A., N.A.)	101	11 (10.9)	N.A. (N.A., N.A.)	1.109 (0.489, 2.515) 0.8034	
STAGE IV	158	21 (13.3)	N.A. (N.A., N.A.)	140	6 (4.3)	N.A. (N.A., N.A.)	2.779 (1.103, 7.002) 0.0237	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:44

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.6731
NEVER	124	13 (10.5)	N.A. (N.A., N.A.)	116	9 (7.8)	N.A. (N.A., N.A.)	1.186 (0.491, 2.862) 0.7043	
FORMER	155	27 (17.4)	N.A. (N.A., N.A.)	153	10 (6.5)	N.A. (N.A., N.A.)	2.316 (1.097, 4.893) 0.0233	
CURRENT	18	3 (16.7)	N.A. (17.31, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.4001	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	1 (14.3)	N.A. (5.78, N.A.)	N.M.E. 0.3865	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.6074
YES	28	5 (17.9)	N.A. (17.31, N.A.)	26	3 (11.5)	N.A. (N.A., N.A.)	1.202 (0.269, 5.373) 0.8092	
NO	272	38 (14.0)	N.A. (N.A., N.A.)	258	17 (6.6)	N.A. (N.A., N.A.)	1.820 (1.007, 3.290) 0.0440	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	43 (14.4)	N.M.E.	284	20 (7.0)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Respiratory, Thoracic and Mediastinal Disorders

Serious Adverse Events with SOC: Respiratory, Thoracic and Mediastinal Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.2216
POSITIVE	229	33 (14.4)	N.A. (N.A., N.A.)	203	17 (8.4)	N.A. (N.A., N.A.)	1.393 (0.756, 2.567) 0.2860	
NEGATIVE	57	7 (12.3)	N.A. (N.A., N.A.)	76	2 (2.6)	N.A. (N.A., N.A.)	4.334 (0.874, 21.481) 0.0499	
NOT REPORTED	14	3 (21.4)	N.A. (2.99, N.A.)	5	1 (20.0)	N.A. (6.77, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	19 (6.3)	N.A. (N.A., N.A.)	284	0	N.A. (N.A., N.A.)	N.M.E. 0.0004	
AGE CATEGORIZATION								>0.9999
< 65	71	5 (7.0)	N.A. (N.A., N.A.)	87	0	N.A. (N.A., N.A.)	N.M.E. 0.0118	
>= 65 AND < 75	151	10 (6.6)	N.A. (N.A., N.A.)	123	0	N.A. (N.A., N.A.)	N.M.E. 0.0395	
>= 75	78	4 (5.1)	N.A. (N.A., N.A.)	74	0	N.A. (N.A., N.A.)	N.M.E. 0.0938	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								>0.9999
MALE	232	14 (6.0)	N.A. (N.A., N.A.)	221	0	N.A. (N.A., N.A.)	N.M.E. 0.0030	
FEMALE	68	5 (7.4)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. 0.0493	
RACE								>0.9999
WHITE	263	14 (5.3)	N.A. (N.A., N.A.)	233	0	N.A. (N.A., N.A.)	N.M.E. 0.0025	
ASIAN	26	5 (19.2)	19.35 (15.93, N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0329	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	2 (6.3)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	8 (4.6)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	5 (19.2)	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	4 (6.0)	N.M.E.	57	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								>0.9999
0	113	9 (8.0)	N.A. (N.A., N.A.)	121	0	N.A. (N.A., N.A.)	N.M.E. 0.0058	
>= 1	187	10 (5.3)	N.A. (N.A., N.A.)	163	0	N.A. (N.A., N.A.)	N.M.E. 0.0193	
IVRS HISTOLOGY								>0.9999
EPITHELIOID	233	14 (6.0)	N.A. (N.A., N.A.)	219	0	N.A. (N.A., N.A.)	N.M.E. 0.0018	
NON-EPITHELIOID	67	5 (7.5)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.0808	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	3 (25.0)	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	2 (8.7)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	5 (4.9)	N.M.E.	101	0	N.M.E.	N.M.E.	
STAGE IV	158	9 (5.7)	N.M.E.	140	0	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	5 (4.0)	N.A. (N.A., N.A.)	116	0	N.A. (N.A., N.A.)	N.M.E. 0.1637	
FORMER	155	13 (8.4)	N.A. (N.A., N.A.)	153	0	N.A. (N.A., N.A.)	N.M.E. 0.0012	
CURRENT	18	1 (5.6)	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5050	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9979
YES	28	0	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	19 (7.0)	N.A. (N.A., N.A.)	258	0	N.A. (N.A., N.A.)	N.M.E. 0.0004	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	19 (6.4)	N.M.E.	284	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Hepatobiliary Disorders

Serious Adverse Events with SOC: Hepatobiliary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9997
POSITIVE	229	17 (7.4)	N.A. (N.A., N.A.)	203	0	N.A. (N.A., N.A.)	N.M.E. 0.0006	
NEGATIVE	57	1 (1.8)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NOT REPORTED	14	1 (7.1)	N.A. (8.61, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	18 (6.0)	N.A. (N.A., N.A.)	284	1 (0.4)	N.A. (N.A., N.A.)	12.809 (1.676, 97.919) 0.0015	
AGE CATEGORIZATION								>0.9999
< 65	71	3 (4.2)	N.A. (N.A., N.A.)	87	0	N.A. (N.A., N.A.)	N.M.E. 0.2739	
>= 65 AND < 75	151	10 (6.6)	N.A. (N.A., N.A.)	123	1 (0.8)	N.A. (N.A., N.A.)	5.939 (0.731, 48.283) 0.0581	
>= 75	78	5 (6.4)	N.A. (N.A., N.A.)	74	0	N.A. (N.A., N.A.)	N.M.E. 0.0230	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:44

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9923
MALE	232	12 (5.2)	N.A. (N.A., N.A.)	221	0	N.A. (N.A., N.A.)	N.M.E. 0.0017	
FEMALE	68	6 (8.8)	N.A. (N.A., N.A.)	63	1 (1.6)	N.A. (N.A., N.A.)	2.852 (0.297, 27.434) 0.3424	
RACE								>0.9999
WHITE	263	17 (6.5)	N.A. (N.A., N.A.)	233	1 (0.4)	N.A. (N.A., N.A.)	11.067 (1.439, 85.124) 0.0037	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.2272	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	4 (12.5)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	7 (4.0)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	1 (3.8)	N.M.E.	38	0	N.M.E.	N.M.E.	
REST OF WORLD	67	6 (9.0)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.9911
0	113	10 (8.8)	N.A. (N.A., N.A.)	121	0	N.A. (N.A., N.A.)	N.M.E. 0.0058	
>= 1	187	8 (4.3)	N.A. (N.A., N.A.)	163	1 (0.6)	N.A. (N.A., N.A.)	5.504 (0.662, 45.742) 0.0756	
IVRS HISTOLOGY								0.9913
EPITHELIOID	233	16 (6.9)	N.A. (N.A., N.A.)	219	1 (0.5)	N.A. (N.A., N.A.)	10.700 (1.381, 82.891) 0.0045	
NON-EPITHELIOID	67	2 (3.0)	N.A. (N.A., N.A.)	65	0	N.A. (N.A., N.A.)	N.M.E. 0.1435	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	0	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	1 (4.3)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	8 (7.8)	N.M.E.	101	1 (1.0)	N.M.E.	N.M.E.	
STAGE IV	158	9 (5.7)	N.M.E.	140	0	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								>0.9999
NEVER	124	6 (4.8)	N.A. (N.A., N.A.)	116	0	N.A. (N.A., N.A.)	N.M.E. 0.0271	
FORMER	155	10 (6.5)	N.A. (N.A., N.A.)	153	1 (0.7)	N.A. (N.A., N.A.)	7.283 (0.896, 59.224) 0.0295	
CURRENT	18	2 (11.1)	N.A. (10.61, N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. 0.5211	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9915
YES	28	1 (3.6)	N.A. (16.16, N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NO	272	17 (6.3)	N.A. (N.A., N.A.)	258	1 (0.4)	N.A. (N.A., N.A.)	12.903 (1.688, 98.641) 0.0014	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	18 (6.0)	N.M.E.	284	1 (0.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Nervous System Disorders

Serious Adverse Events with SOC: Nervous System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9933
POSITIVE	229	15 (6.6)	N.A. (N.A., N.A.)	203	1 (0.5)	N.A. (N.A., N.A.)	10.000 (1.291, 77.469) 0.0064	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. 0.0937	
NOT REPORTED	14	1 (7.1)	N.A. (16.16, N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	13 (4.3)	N.A. (N.A., N.A.)	284	3 (1.1)	N.A. (N.A., N.A.)	3.653 (1.019, 13.095) 0.0331	
AGE CATEGORIZATION								N.M.E.
< 65	71	2 (2.8)	N.M.E.	87	1 (1.1)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	5 (3.3)	N.M.E.	123	1 (0.8)	N.M.E.	N.M.E.	
>= 75	78	6 (7.7)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9935
MALE	232	12 (5.2)	N.A. (N.A., N.A.)	221	3 (1.4)	N.A. (N.A., N.A.)	3.689 (1.029, 13.228) 0.0317	
FEMALE	68	1 (1.5)	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
RACE								0.7413
WHITE	263	12 (4.6)	N.A. (N.A., N.A.)	233	2 (0.9)	N.A. (N.A., N.A.)	4.669 (1.023, 21.307) 0.0284	
ASIAN	26	1 (3.8)	N.A. (N.A., N.A.)	38	1 (2.6)	N.A. (N.A., N.A.)	1.532 (0.096, 24.501) 0.7611	
OTHER	11	0	N.A. (N.A., N.A.)	13	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	2 (6.3)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	8 (4.6)	N.M.E.	164	1 (0.6)	N.M.E.	N.M.E.	
ASIA	26	1 (3.8)	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
REST OF WORLD	67	2 (3.0)	N.M.E.	57	1 (1.8)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	9 (8.0)	N.M.E.	121	0	N.M.E.	N.M.E.	
>= 1	187	4 (2.1)	N.M.E.	163	3 (1.8)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								0.0486**
EPITHELIOID	233	12 (5.2)	N.A. (N.A., N.A.)	219	1 (0.5)	N.A. (N.A., N.A.)	10.033 (1.284, 78.386) 0.0066	
NON-EPITHELIOID	67	1 (1.5)	N.A. (N.A., N.A.)	65	2 (3.1)	N.A. (N.A., N.A.)	0.503 (0.046, 5.545) 0.5669	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								>0.9999
STAGE I	12	1 (8.3)	N.A. (N.A., N.A.)	17	0	N.A. (N.A., N.A.)	N.M.E. 0.2340	
STAGE II	23	1 (4.3)	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. 0.3291	
STAGE III	102	4 (3.9)	N.A. (N.A., N.A.)	101	0	N.A. (N.A., N.A.)	N.M.E. 0.0791	
STAGE IV	158	7 (4.4)	N.A. (N.A., N.A.)	140	3 (2.1)	N.A. (N.A., N.A.)	1.826 (0.457, 7.305) 0.3873	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	5 (4.0)	N.M.E.	116	1 (0.9)	N.M.E.	N.M.E.	
FORMER	155	7 (4.5)	N.M.E.	153	2 (1.3)	N.M.E.	N.M.E.	
CURRENT	18	1 (5.6)	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.2483
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	0.886 (0.055, 14.173) 0.9320	
NO	272	12 (4.4)	N.A. (N.A., N.A.)	258	2 (0.8)	N.A. (N.A., N.A.)	5.036 (1.103, 22.986) 0.0203	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	13 (4.3)	N.M.E.	284	3 (1.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Renal and Urinary Disorders

Serious Adverse Events with SOC: Renal and Urinary Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9995
POSITIVE	229	13 (5.7)	N.A. (N.A., N.A.)	203	2 (1.0)	N.A. (N.A., N.A.)	5.129 (1.137, 23.139) 0.0177	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	1 (20.0)	N.A. (1.02, N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	10 (3.3)	N.A. (N.A., N.A.)	284	1 (0.4)	N.A. (N.A., N.A.)	7.723 (0.966, 61.752) 0.0226	
AGE CATEGORIZATION								N.M.E.
< 65	71	2 (2.8)	N.M.E.	87	0	N.M.E.	N.M.E.	
>= 65 AND < 75	151	6 (4.0)	N.M.E.	123	0	N.M.E.	N.M.E.	
>= 75	78	2 (2.6)	N.M.E.	74	1 (1.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.9995
MALE	232	10 (4.3)	N.A. (N.A., N.A.)	221	1 (0.5)	N.A. (N.A., N.A.)	7.764 (0.971, 62.079) 0.0221	
FEMALE	68	0	N.A. (N.A., N.A.)	63	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
RACE								N.M.E.
WHITE	263	6 (2.3)	N.M.E.	233	0	N.M.E.	N.M.E.	
ASIAN	26	4 (15.4)	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
OTHER	11	0	N.M.E.	13	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								N.M.E.
NORTH AMERICA	32	1 (3.1)	N.M.E.	25	0	N.M.E.	N.M.E.	
EUROPE	175	3 (1.7)	N.M.E.	164	0	N.M.E.	N.M.E.	
ASIA	26	4 (15.4)	N.M.E.	38	1 (2.6)	N.M.E.	N.M.E.	
REST OF WORLD	67	2 (3.0)	N.M.E.	57	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								N.M.E.
0	113	7 (6.2)	N.M.E.	121	0	N.M.E.	N.M.E.	
>= 1	187	3 (1.6)	N.M.E.	163	1 (0.6)	N.M.E.	N.M.E.	
IVRS HISTOLOGY								N.M.E.
EPITHELIOID	233	9 (3.9)	N.M.E.	219	0	N.M.E.	N.M.E.	
NON-EPITHELIOID	67	1 (1.5)	N.M.E.	65	1 (1.5)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								N.M.E.
STAGE I	12	0	N.M.E.	17	0	N.M.E.	N.M.E.	
STAGE II	23	1 (4.3)	N.M.E.	21	0	N.M.E.	N.M.E.	
STAGE III	102	3 (2.9)	N.M.E.	101	0	N.M.E.	N.M.E.	
STAGE IV	158	6 (3.8)	N.M.E.	140	1 (0.7)	N.M.E.	N.M.E.	
NOT REPORTED	5	0	N.M.E.	5	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								N.M.E.
NEVER	124	3 (2.4)	N.M.E.	116	0	N.M.E.	N.M.E.	
FORMER	155	7 (4.5)	N.M.E.	153	1 (0.7)	N.M.E.	N.M.E.	
CURRENT	18	0	N.M.E.	8	0	N.M.E.	N.M.E.	
UNKNOWN	3	0	N.M.E.	7	0	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9949
YES	28	1 (3.6)	N.A. (N.A., N.A.)	26	0	N.A. (N.A., N.A.)	N.M.E. 0.3447	
NO	272	9 (3.3)	N.A. (N.A., N.A.)	258	1 (0.4)	N.A. (N.A., N.A.)	6.832 (0.841, 55.533) 0.0369	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	10 (3.3)	N.M.E.	284	1 (0.4)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Endocrine Disorders

Serious Adverse Events with SOC: Endocrine Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.9996
POSITIVE	229	9 (3.9)	N.A. (N.A., N.A.)	203	1 (0.5)	N.A. (N.A., N.A.)	6.150 (0.757, 49.984) 0.0521	
NEGATIVE	57	0	N.A. (N.A., N.A.)	76	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
NOT REPORTED	14	1 (7.1)	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	300	7 (2.3)	N.A. (N.A., N.A.)	284	16 (5.6)	N.A. (N.A., N.A.)	0.296 (0.108, 0.807) 0.0115	
AGE CATEGORIZATION								N.M.E.
< 65	71	3 (4.2)	N.M.E.	87	5 (5.7)	N.M.E.	N.M.E.	
>= 65 AND < 75	151	2 (1.3)	N.M.E.	123	5 (4.1)	N.M.E.	N.M.E.	
>= 75	78	2 (2.6)	N.M.E.	74	6 (8.1)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
SEX								0.5643
MALE	232	5 (2.2)	N.A. (N.A., N.A.)	221	10 (4.5)	N.A. (N.A., N.A.)	0.289 (0.079, 1.049) 0.0443	
FEMALE	68	2 (2.9)	N.A. (N.A., N.A.)	63	6 (9.5)	N.A. (N.A., N.A.)	0.302 (0.061, 1.497) 0.1199	
RACE								0.9999
WHITE	263	5 (1.9)	N.A. (N.A., N.A.)	233	14 (6.0)	N.A. (N.A., N.A.)	0.188 (0.054, 0.655) 0.0033	
ASIAN	26	2 (7.7)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0842	
OTHER	11	0	N.A. (N.A., N.A.)	13	2 (15.4)	N.A. (3.38, N.A.)	N.M.E. 0.1869	

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Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:44

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
REGION								0.8464
NORTH AMERICA	32	1 (3.1)	N.A. (N.A., N.A.)	25	0	N.A. (N.A., N.A.)	N.M.E. 0.3768	
EUROPE	175	2 (1.1)	N.A. (N.A., N.A.)	164	12 (7.3)	N.A. (N.A., N.A.)	0.153 (0.034, 0.685) 0.0046	
ASIA	26	2 (7.7)	N.A. (N.A., N.A.)	38	0	N.A. (N.A., N.A.)	N.M.E. 0.0842	
REST OF WORLD	67	2 (3.0)	N.A. (N.A., N.A.)	57	4 (7.0)	N.A. (N.A., N.A.)	<0.001 (<0.001, N.A.) 0.0332	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:44

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
ECOG PERFORMANCE STATUS								0.0989
0	113	4 (3.5)	N.A. (N.A., N.A.)	121	4 (3.3)	N.A. (N.A., N.A.)	0.538 (0.099, 2.937) 0.4668	
>= 1	187	3 (1.6)	N.A. (N.A., N.A.)	163	12 (7.4)	N.A. (N.A., N.A.)	0.217 (0.061, 0.768) 0.0091	
IVRS HISTOLOGY								0.5304
EPITHELIOID	233	5 (2.1)	N.A. (N.A., N.A.)	219	9 (4.1)	N.A. (N.A., N.A.)	0.314 (0.085, 1.159) 0.0663	
NON-EPITHELIOID	67	2 (3.0)	N.A. (N.A., N.A.)	65	7 (10.8)	N.A. (N.A., N.A.)	0.274 (0.057, 1.322) 0.0842	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:44

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE STAGE AT STUDY ENTRY								0.9673
STAGE I	12	0	N.A. (N.A., N.A.)	17	1 (5.9)	N.A. (N.A., N.A.)	N.M.E. 0.4008	
STAGE II	23	0	N.A. (N.A., N.A.)	21	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
STAGE III	102	2 (2.0)	N.A. (N.A., N.A.)	101	6 (5.9)	N.A. (N.A., N.A.)	0.167 (0.020, 1.383) 0.0586	
STAGE IV	158	5 (3.2)	N.A. (N.A., N.A.)	140	9 (6.4)	N.A. (N.A., N.A.)	0.396 (0.122, 1.284) 0.1098	
NOT REPORTED	5	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:44

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
TOBACCO USE								0.9996
NEVER	124	3 (2.4)	N.A. (N.A., N.A.)	116	7 (6.0)	N.A. (N.A., N.A.)	0.265 (0.055, 1.275) 0.0749	
FORMER	155	4 (2.6)	N.A. (N.A., N.A.)	153	9 (5.9)	N.A. (N.A., N.A.)	0.335 (0.091, 1.237) 0.0848	
CURRENT	18	0	N.A. (N.A., N.A.)	8	0	N.A. (N.A., N.A.)	N.M.E. N.A.	
UNKNOWN	3	0	N.A. (N.A., N.A.)	7	0	N.A. (N.A., N.A.)	N.M.E. N.A.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/tables/rt-ae-tsubsoc-ebr2252-batch3.sas 04FEB2021:13:43:44

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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PRIOR RADIOTHERAPY								0.9902
YES	28	0	N.A. (N.A., N.A.)	26	1 (3.8)	N.A. (N.A., N.A.)	N.M.E. 0.2971	
NO	272	7 (2.6)	N.A. (N.A., N.A.)	258	15 (5.8)	N.A. (N.A., N.A.)	0.317 (0.115, 0.873) 0.0189	
PRIOR SYSTEMIC CANCER THERAPY								N.M.E.
YES	1	0	N.M.E.	0	0	N.M.E.	N.M.E.	
NO	299	7 (2.3)	N.M.E.	284	16 (5.6)	N.M.E.	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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Subgroup Time-Adjusted Analyses of Adverse Events
for Serious Adverse Events
by Significant SOC/PT on Hazard Ratio
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Serious Adverse Events with SOC: Blood and Lymphatic System Disorders Subgroup	Nivo + Ipi N	Nivo + Ipi Patients with Event n (%)	Nivo + Ipi KME [95%CI] (mon) (1)	Chemo N	Chemo Patients with Event n (%)	Chemo KME [95%CI] (mon) (1)	Nivo + Ipi vs. Chemo HR [95%CI] P-value (2)(3)	Test for Interaction P-value (4)(5)
PD-L1								0.5131
POSITIVE	229	5 (2.2)	N.A. (N.A., N.A.)	203	12 (5.9)	N.A. (N.A., N.A.)	0.218 (0.062, 0.773) 0.0095	
NEGATIVE	57	2 (3.5)	N.A. (N.A., N.A.)	76	4 (5.3)	N.A. (N.A., N.A.)	0.700 (0.128, 3.822) 0.6803	
NOT REPORTED	14	0	N.A. (N.A., N.A.)	5	0	N.A. (N.A., N.A.)	N.M.E.	

April 2020 DBL. MedDRA Version: 22.1 CTC Version 4.0. HR = hazard ratio; KME=Kaplan-Meier estimate.
Includes events reported between first dose and 100 days after last dose of study therapy. (1) KME of median time.
If there are no patients with events in nivo + ipi or chemotherapy in one subgroup, display HR as n.m.e.
(2) Unstratified Cox proportional hazard model. HR is Nivo +Ipi over Chemotherapy (3) Unstratified log-rank test.
(4) Unstratified Cox proportional hazard model with treatment, subgroup and treatment*subgroup interaction is to assess the significance of the interaction between treatment and the subgroup.
(5) A p-value of <0.05 needs to be indicated by 2 asterisks (proof of different effects).
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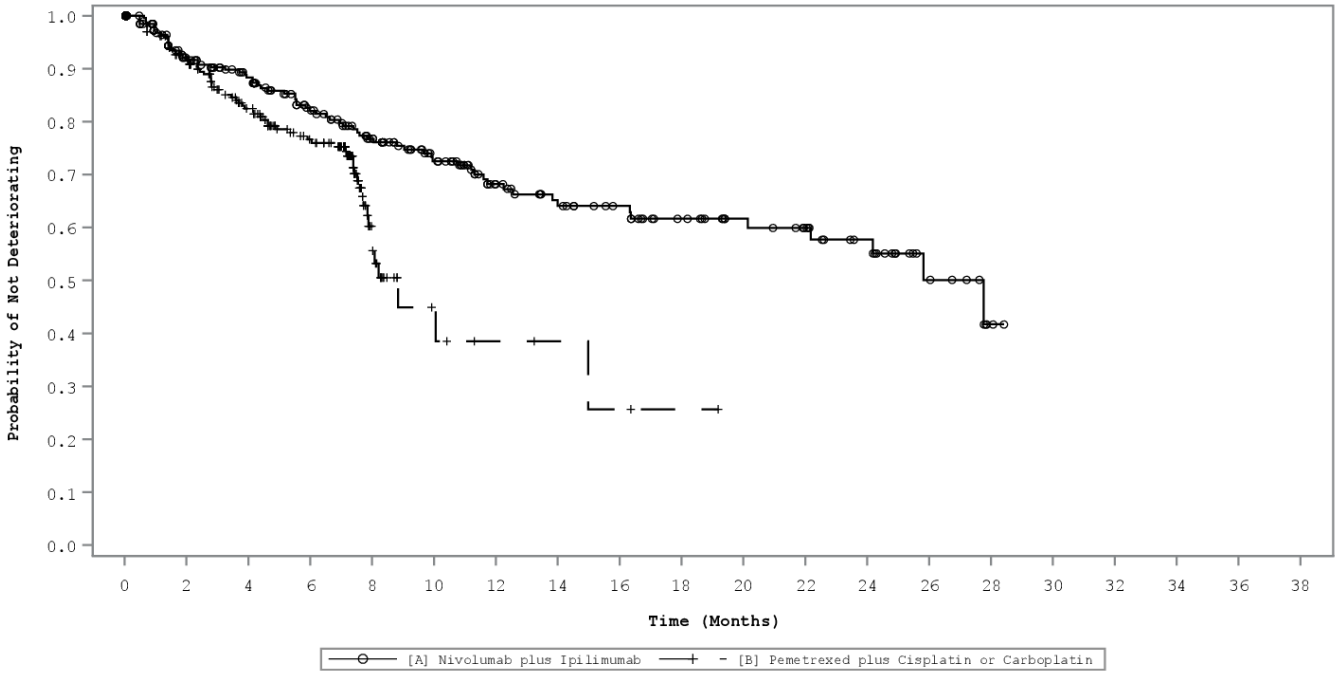
Anhang 4-G 5: Kaplan-Meier-Kurven aus CA209-743

Anhang 4-G 5.1: Kaplan-Meier-Kurven für Endpunkte aus CA209-743

Anhang 4-G 5.1.1: Kaplan-Meier-Kurven für Endpunkte Morbidität und Lebensqualität aus CA209-743

Für die Endpunkte Appetitlosigkeit, Fatigue, Husten, Dyspnoe, Schmerz, Symptombelastung, Aktivitätsbeeinträchtigung, allgemeine gesundheitsbezogene Lebensqualität, Index-Wert der krankheitsbedingten Symptome (MID 15 mm) und den Index-Wert der gesundheitsbezogenen Lebensqualität gemäß LCSS-Meso (MID 45 mm) sowie den Gesundheitszustand gemäß EQ-5D-VAS (MID 7 mm) – Zeit bis zur dauerhaften Verschlechterung

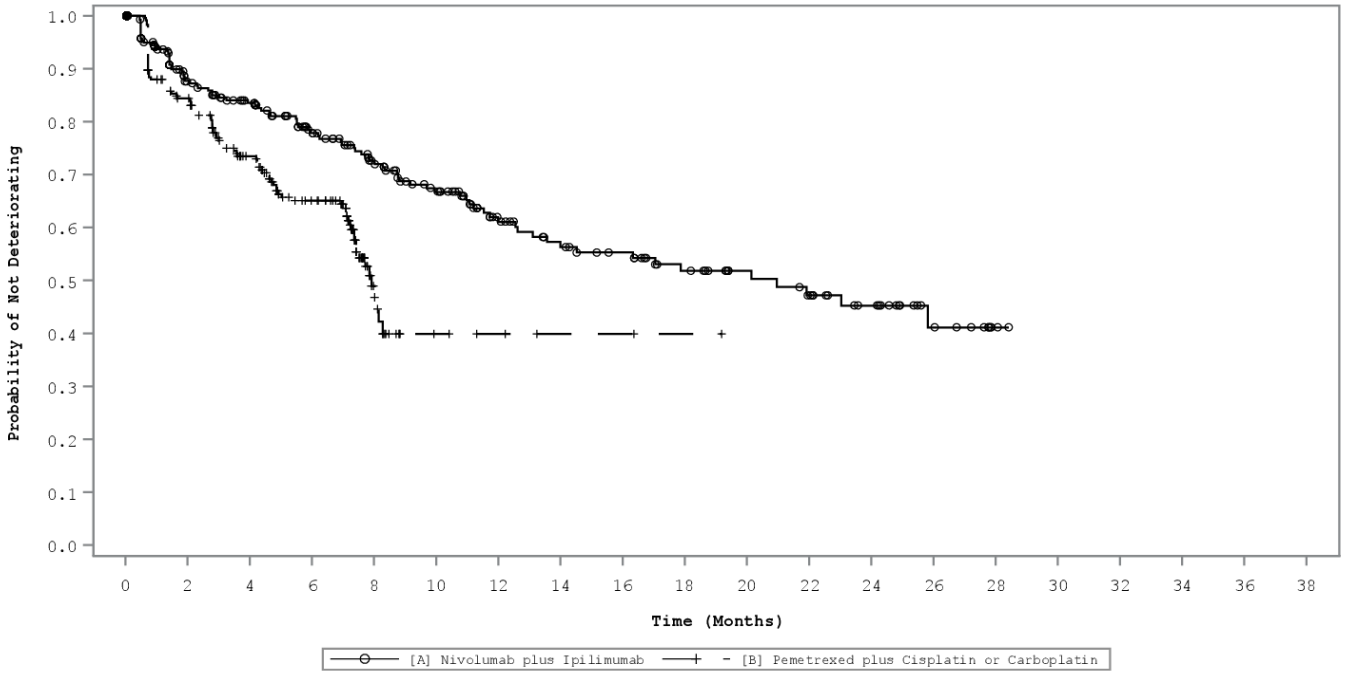
Figure 2.1.2.2 Time to Definitive Deterioration for LCSS: Anorexia (Appetite) (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	205	180	148	122	98	71	60	53	43	35	30	22	10	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	207	157	116	26	7	4	3	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:10 by alejandro.moreno-koe

Figure 2.1.2.4 Time to Definitive Deterioration for LCSS: Fatigue (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	195	173	142	118	96	69	58	52	42	34	29	21	10	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	187	141	102	23	6	4	2	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
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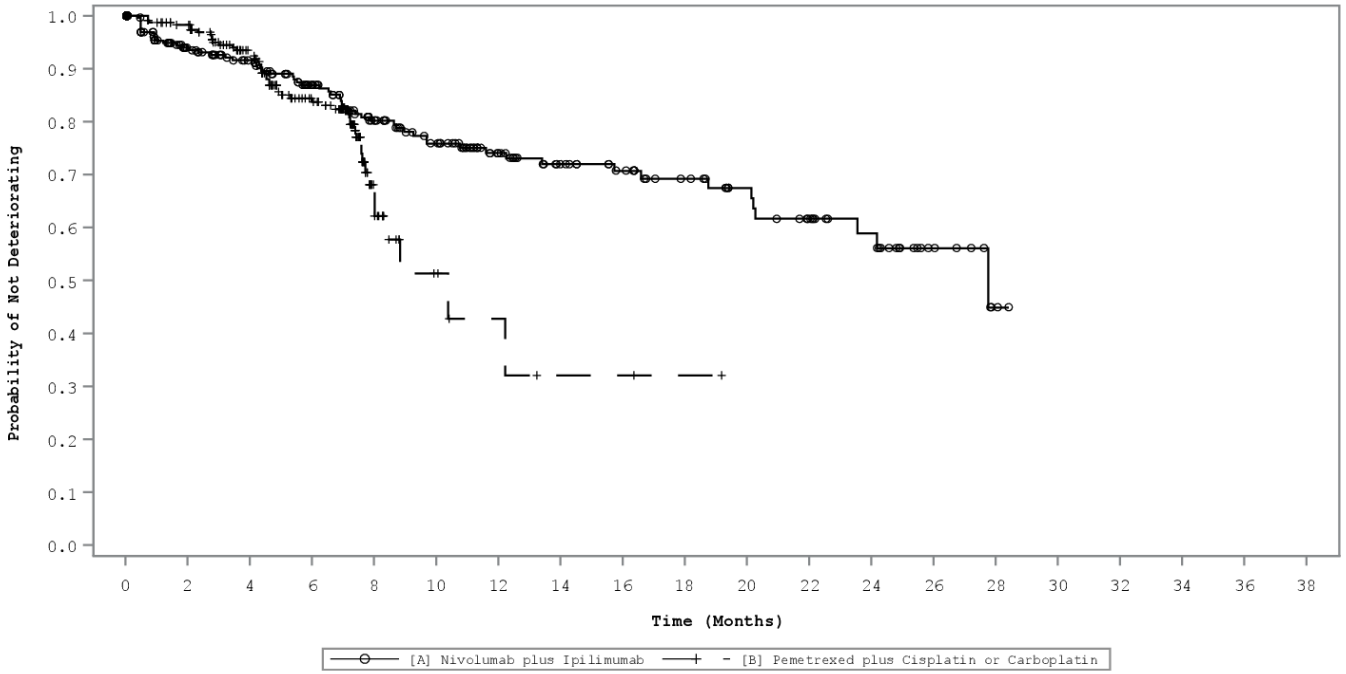
Figure 2.1.2.6 Time to Definitive Deterioration for LCSS: Cough (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	206	183	152	122	101	75	61	53	43	35	28	21	9	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	219	174	126	23	7	4	2	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
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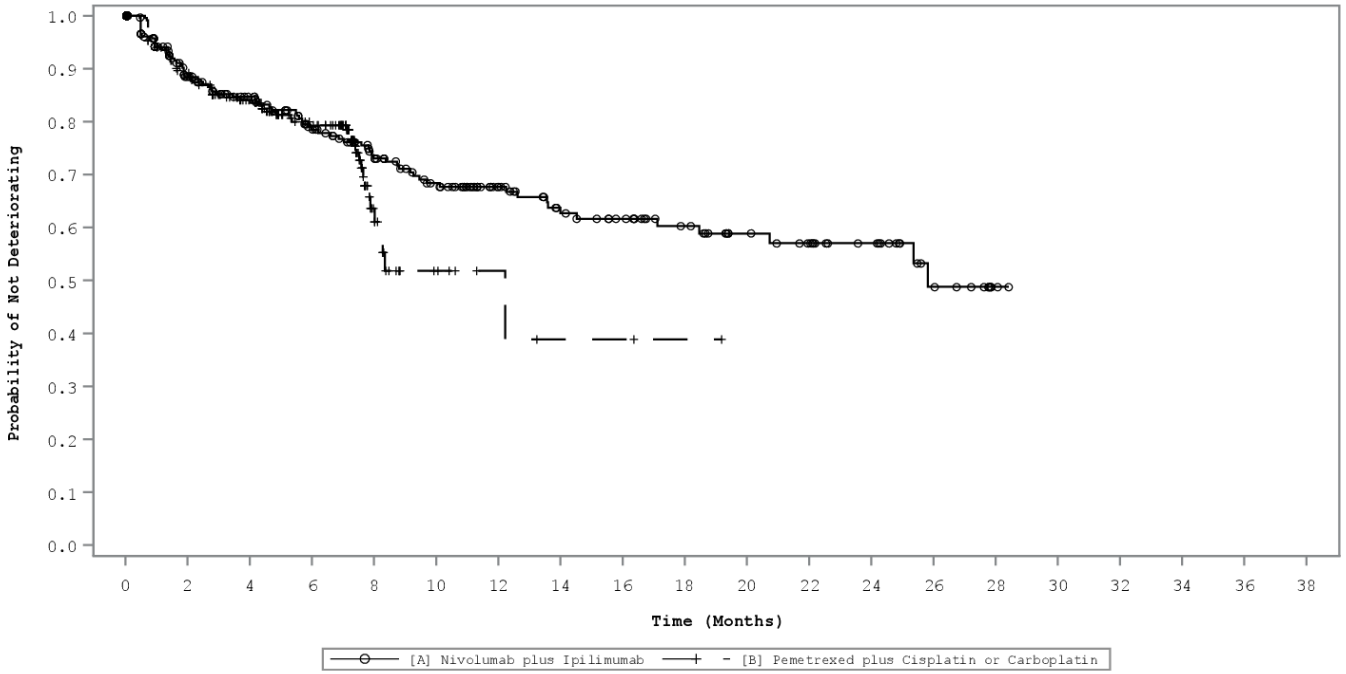
Figure 2.1.2.8 Time to Definitive Deterioration for LCSS: Dyspnea (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	197	174	142	118	98	74	60	53	43	34	29	22	11	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	203	159	119	25	8	4	2	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
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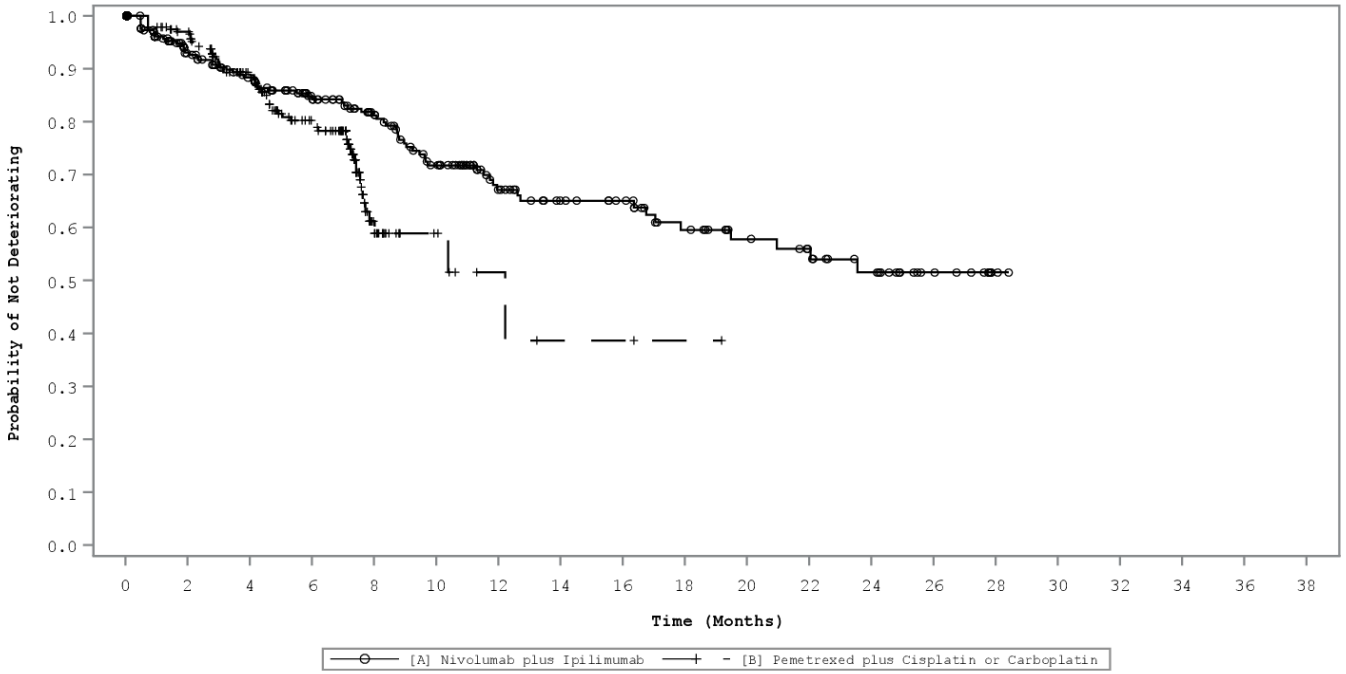
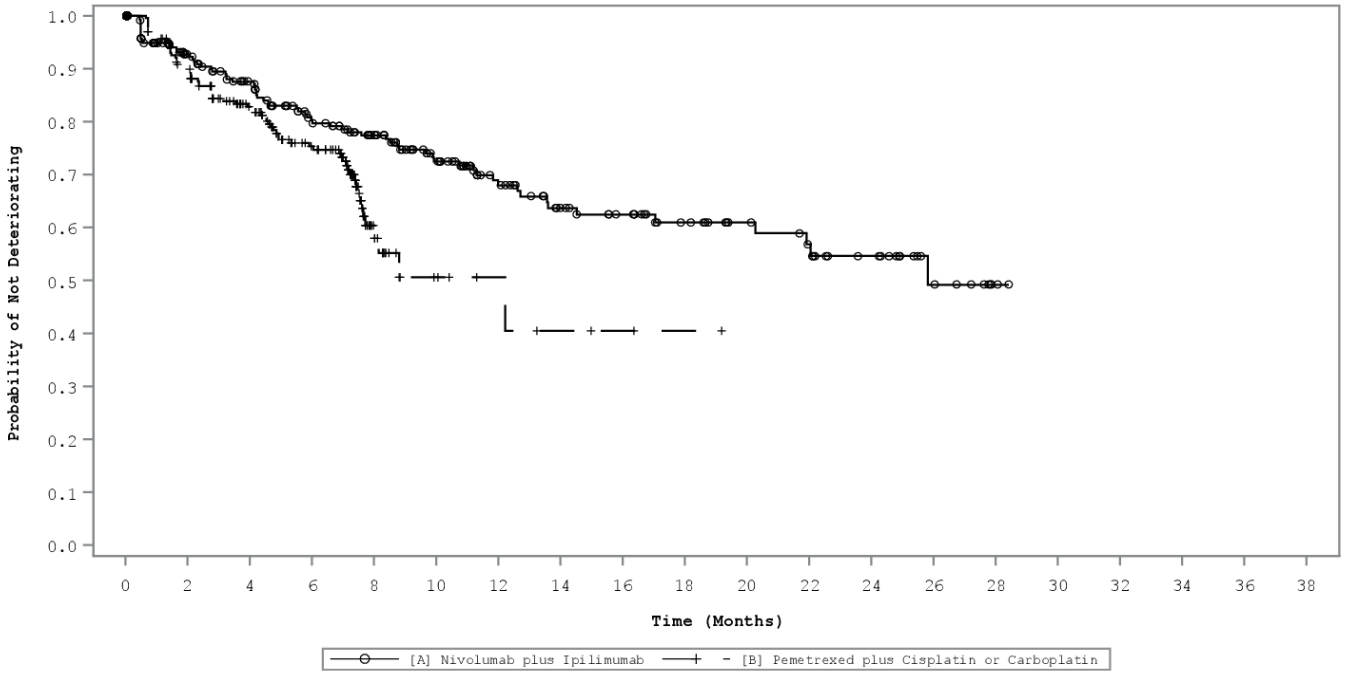
Figure 2.1.2.10 Time to Definitive Deterioration for LCSS: Pain (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	206	182	152	127	101	70	58	53	41	33	28	21	11	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	215	168	121	27	9	4	2	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:14 by alejandro.moreno-koe

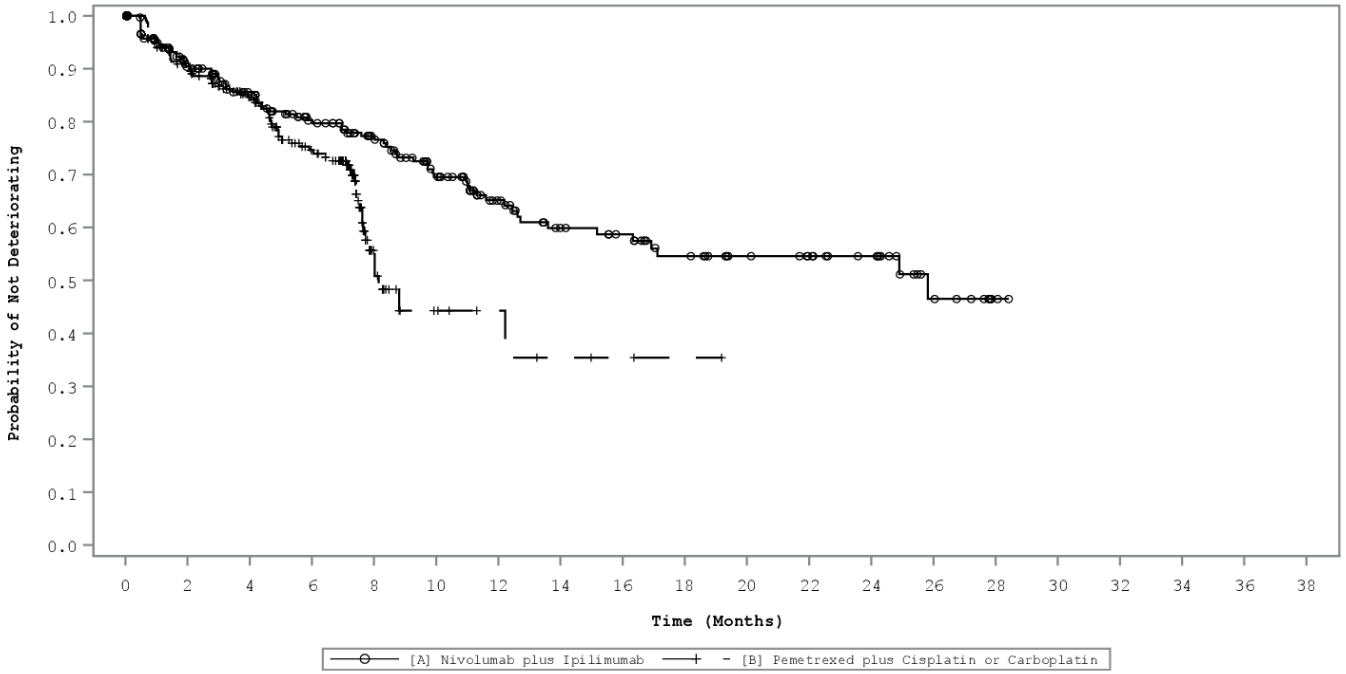
Figure 2.1.2.12 Time to Definitive Deterioration for LCSS: Symptom Distress (reversed) (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	202	177	145	124	97	70	55	48	38	31	26	19	9	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	203	157	117	25	8	5	3	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:15 by alejandro.moreno-koe

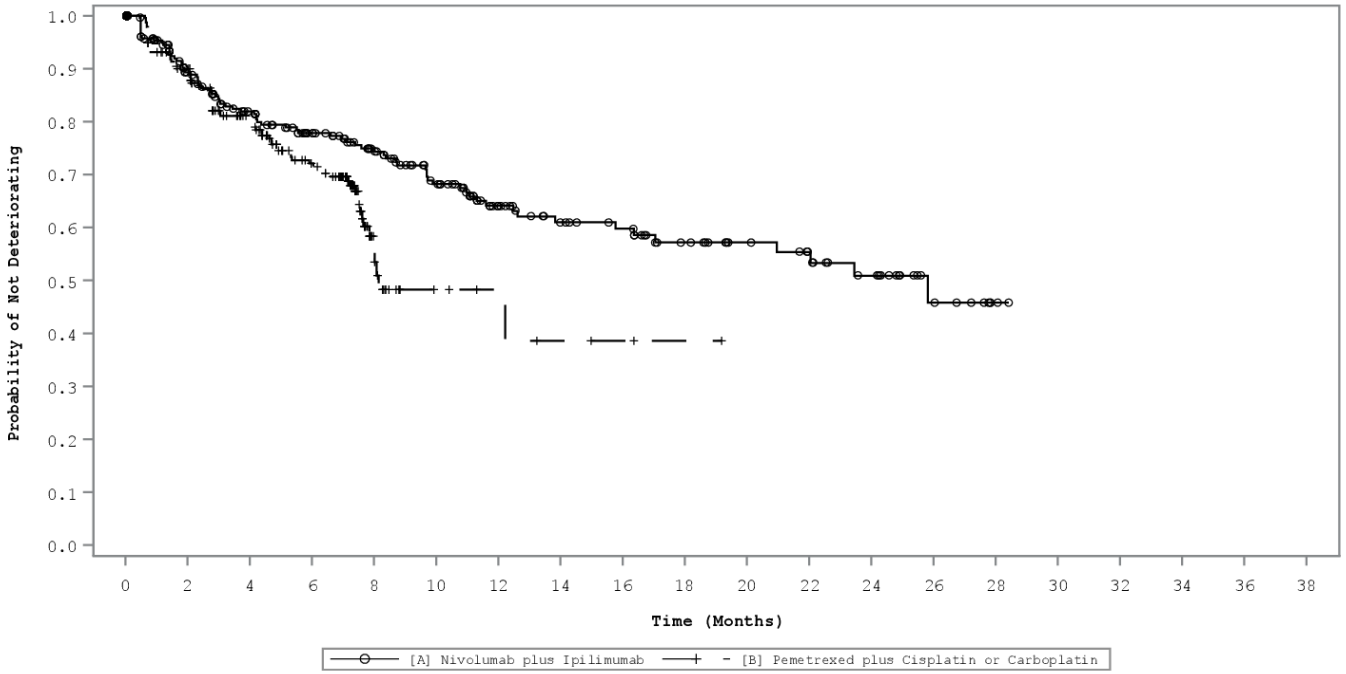
Figure 2.1.2.14 Time to Definitive Deterioration for LCSS: Interference with Activity Level (reversed) (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	195	168	140	118	92	66	52	47	38	31	27	22	10	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	203	159	113	23	8	5	3	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:16 by alejandro.moreno-koe

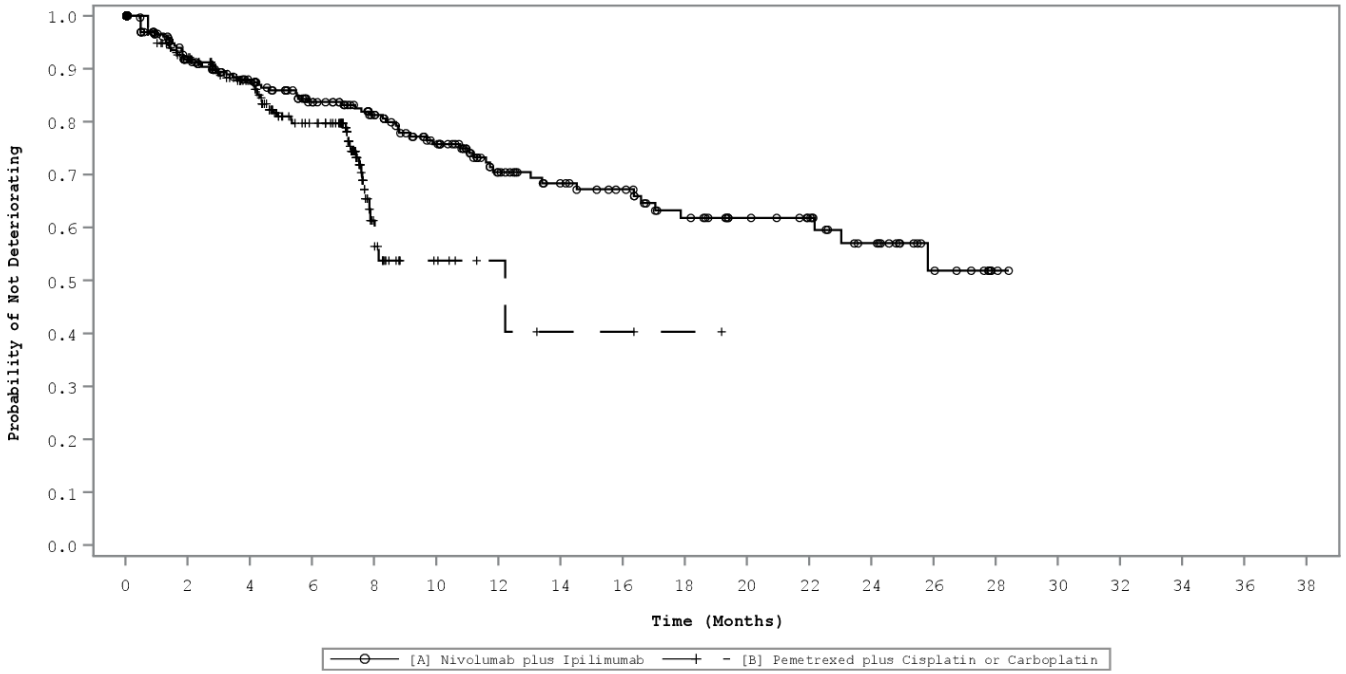
Figure 2.1.2.16 Time to Definitive Deterioration for LCSS: Global HRQoL (reversed) (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	199	168	142	120	96	67	55	50	39	32	27	20	9	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	201	154	116	24	7	5	3	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:17 by alejandro.moreno-koe

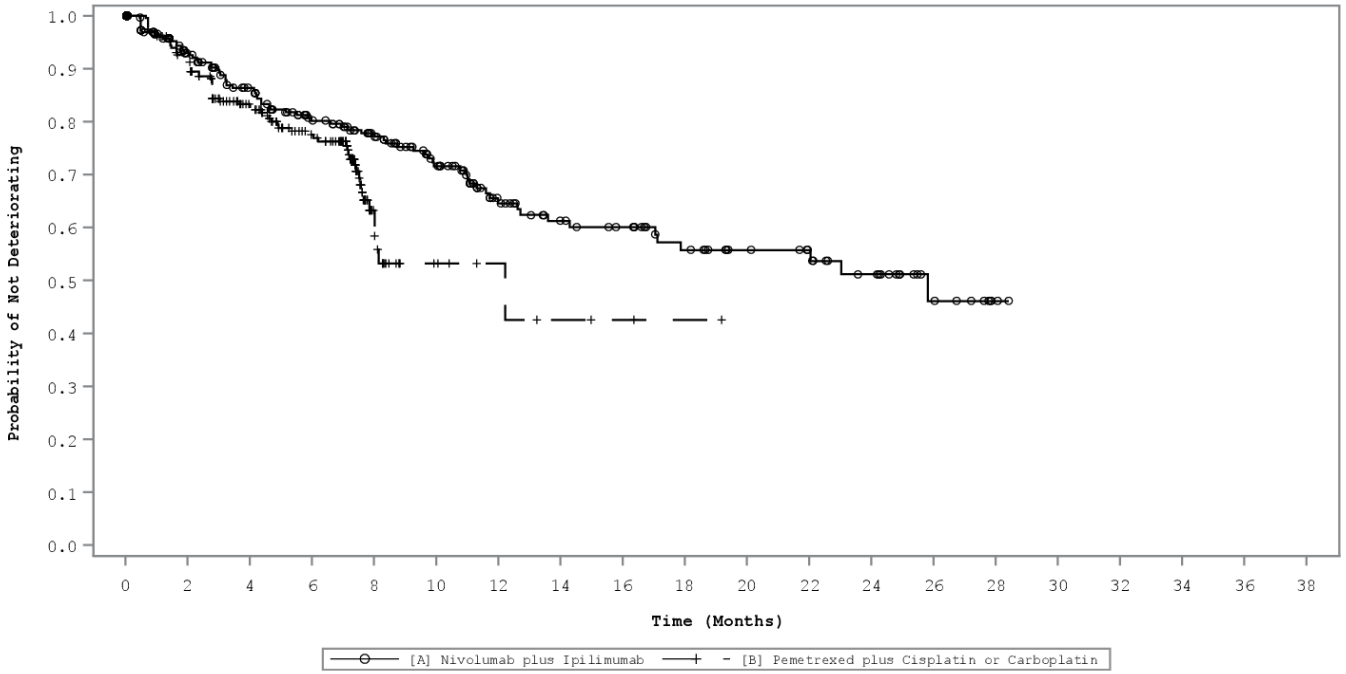
Figure 2.1.2.18 Time to Definitive Deterioration for LCSS: ASBI (MID=15) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	202	178	148	126	103	73	62	55	43	35	30	21	10	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	205	163	119	25	8	4	2	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:18 by alejandro.moreno-koe

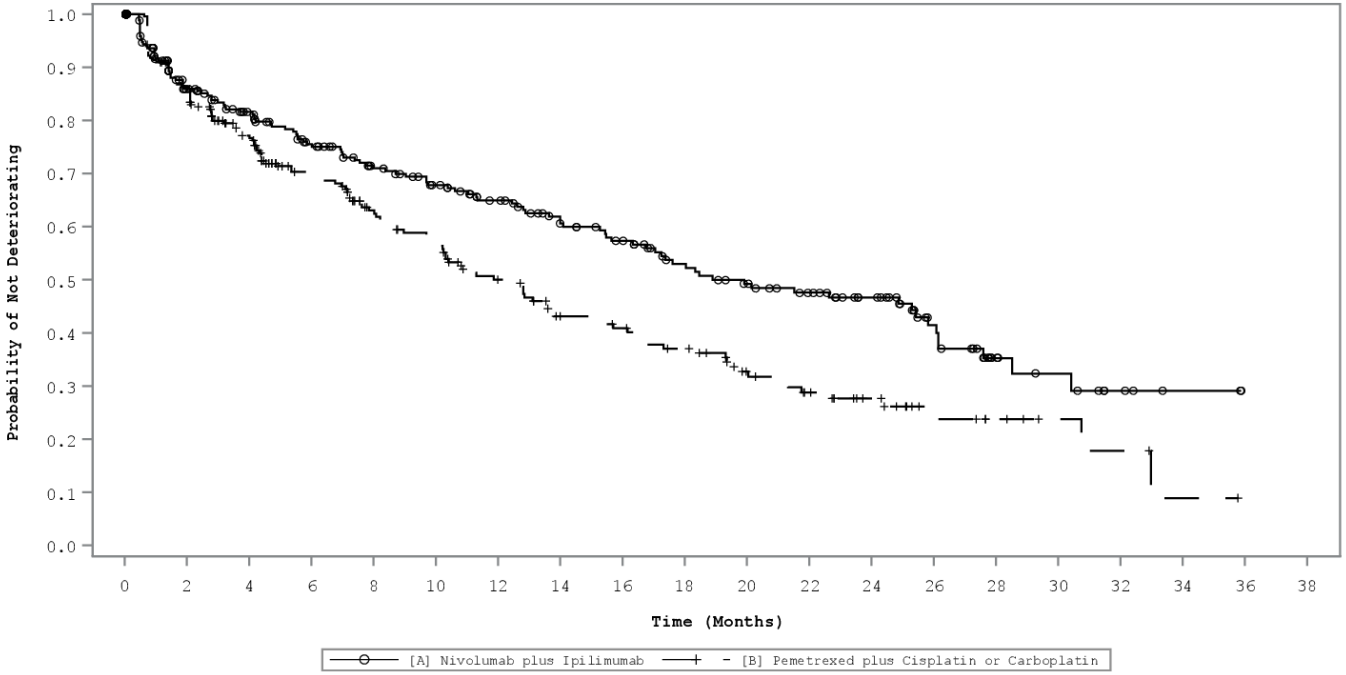
Figure 2.1.2.20 Time to Definitive Deterioration for LCSS: Three-item Index (MID=45) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	204	174	144	123	97	65	53	48	38	31	27	20	9	2	0	0	0	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	208	157	120	26	8	5	3	2	1	0	0	0	0	0	0	0	0	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:19 by alejandro.moreno-koe

Figure 2.1.2.21 Time to Definitive Deterioration for EQ-5D-3L: VAS (MID=7) (Randomized Population) (N=605)



[A] Nivolumab plus Ipilimumab																			
303	204	180	156	137	124	110	94	85	71	63	55	45	28	14	10	5	2	0	0
[B] Pemetrexed plus Cisplatin or Carboplatin																			
302	206	165	129	105	93	75	58	54	47	34	27	19	10	7	4	3	1	0	0

The time to definitive deterioration event was calculated using on-treatment and follow-up timepoints. PRO event was defined as the time from randomization until the first deterioration in PRO score meeting or exceeding the MID/responder definition threshold corresponding to that score without any further improvement afterwards or only missing data after deterioriation. Patients without deterioration are censored at their last PRO assessment time point. Patients without any PRO measurement are censored at baseline.
PROGRAM: \\global.adelphigroup.com\AV\SHARED\Projs\US\BS8720A (743)\Datasets\Analysis\Programs\AMNOG\BS8720A-743 -07.00- AMNOG KM Figures_v0_6.sas EXECUTED: May 12, 2021 at 13:37:20 by alejandro.moreno-koe

Anhang 4-G 5.1.2: Kaplan-Meier-Kurven für Endpunkte Verträglichkeit aus CA209-743

Für die Endpunkte unerwünschte Ereignisse ohne Erfassung des Progresses der Grunderkrankung – Zeit bis zum ersten Auftreten des UE: jegliches UE, UE Grad ≥ 3, schwerwiegende UE und Therapieabbruch wegen UE

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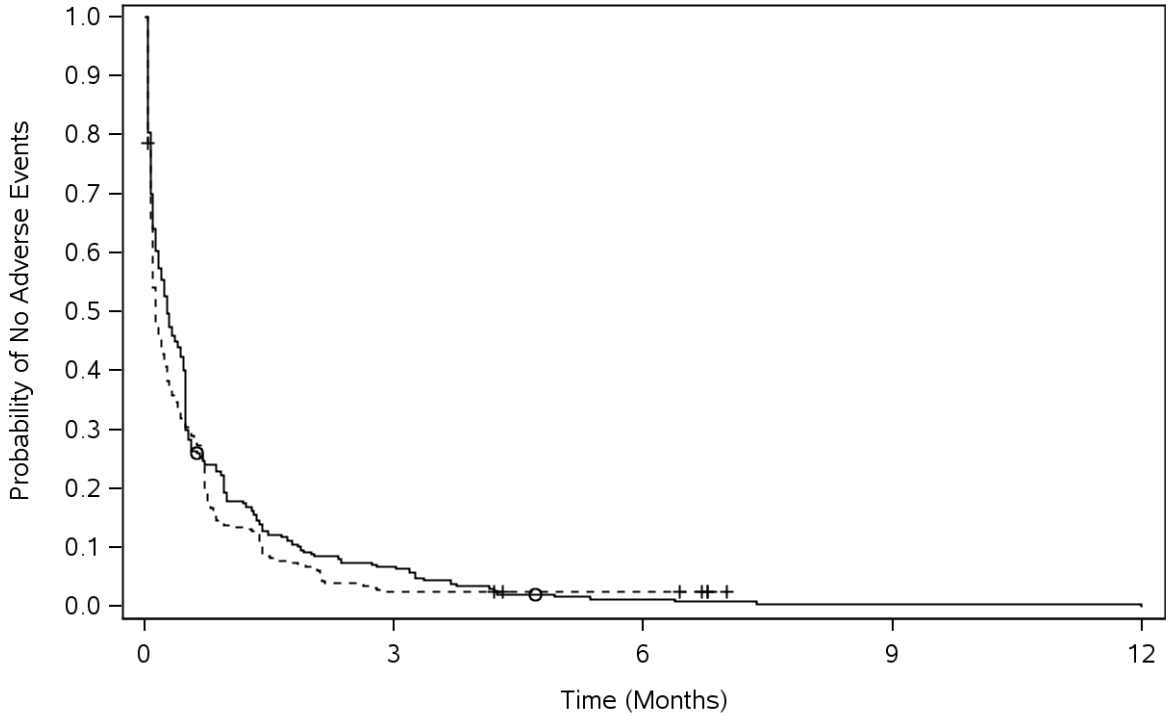
Figure 100.4:
Kaplan-Meier Plot of Time to any - Adverse Events - Excluding Progression Terms - All Treated Subjects



Number of Subjects at Risk

Nivo + Ipi	300	20	3	1	0
Chemo	284	7	5	0	0

—o— Nivo + Ipi (events: 298/300), median and 95% CI: 0.26 (0.20, 0.39)
--+-- Chemo (events: 276/284), median and 95% CI: 0.13 (0.10, 0.20)
Hazard Ratio (Nivo + Ipi vs Chemo) and 95% CI: 0.869 (0.736, 1.025)

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
Hazard ratio computed using a stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ebr2252-batch1.sas 07DEC2020:11:09:19

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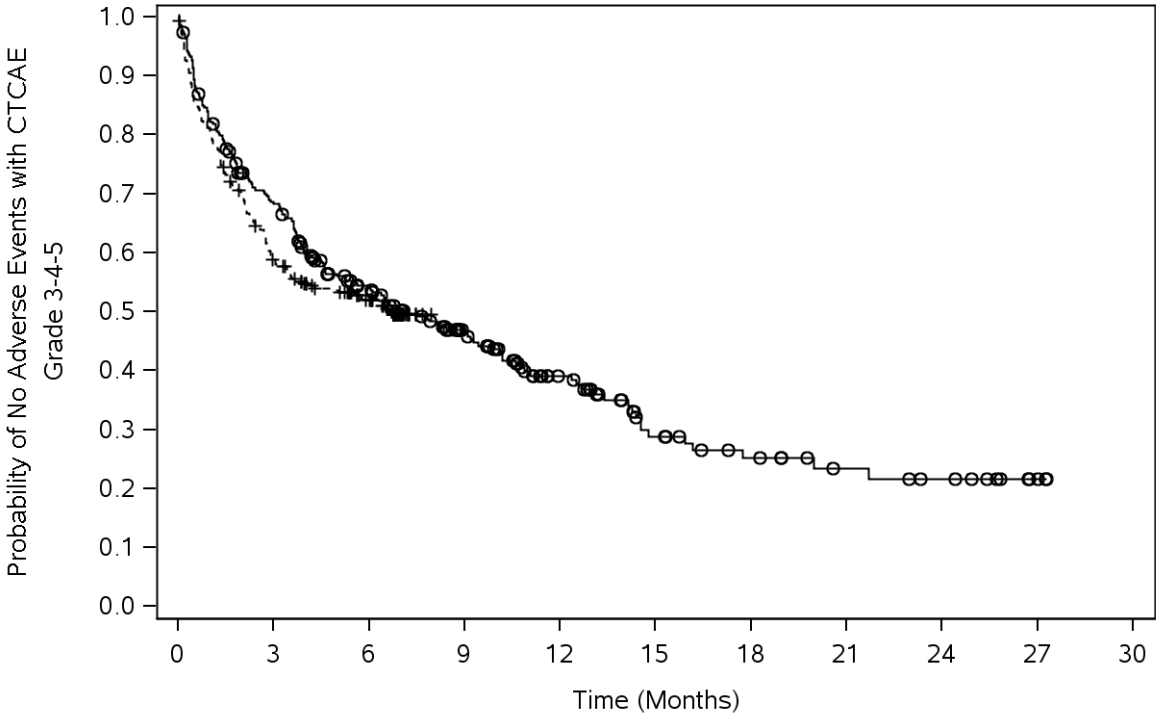
Figure 100.6:
Kaplan-Meier Plot of Time to any - Adverse Events with CTCAE Grade 3-4-5 - Excluding Progression Terms - All Treated Subjects



Number of Subjects at Risk

Nivo + Ipi	300	196	129	86	51	27	19	13	10	3	0
Chemo	284	162	119	0	0	0	0	0	0	0	0

—o— Nivo + Ipi (events: 178/300), median and 95% CI: 7.13 (5.26, 9.79)
- -+- - Chemo (events: 139/284), median and 95% CI: 6.77 (3.55, N.A.)
Hazard Ratio (Nivo + Ipi vs Chemo) and 95% CI: 0.907 (0.718, 1.147)

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
Hazard ratio computed using a stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ebr2252-batch1.sas 07DEC2020:11:08:03

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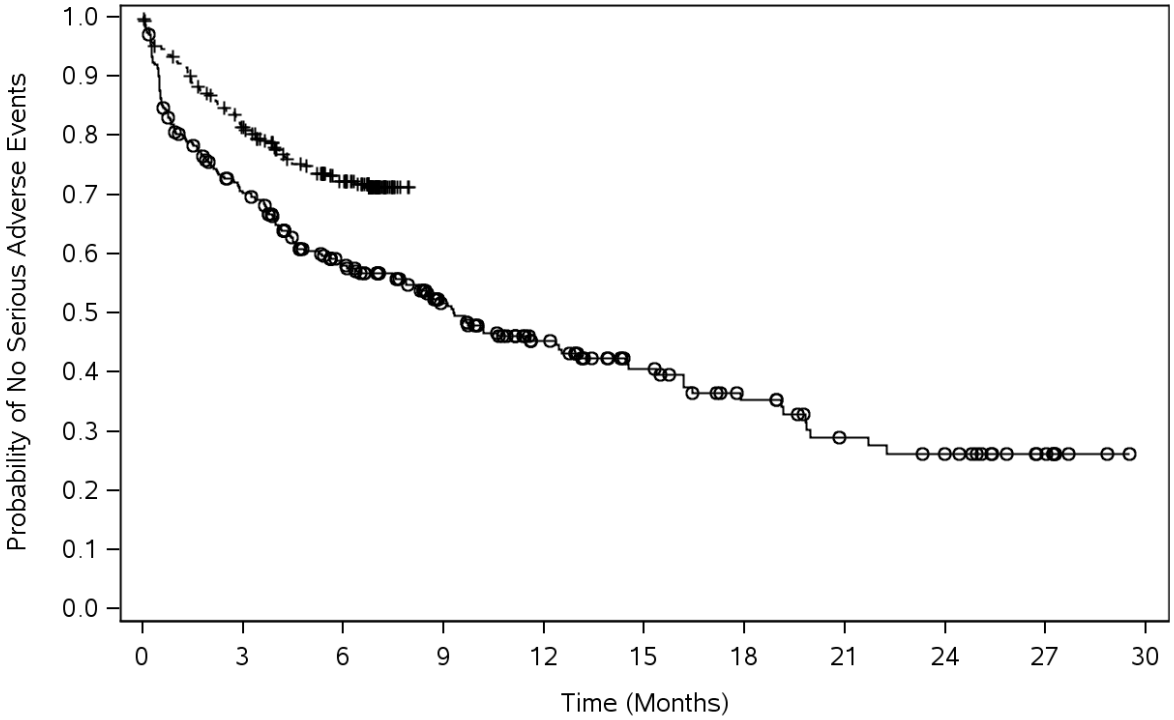
Figure 100.7:
Kaplan-Meier Plot of Time to any - Serious Adverse Events - Excluding Progression Terms - All Treated Subjects



Number of Subjects at Risk

Nivo + Ipi	300	201	138	93	63	43	31	21	17	8	0
Chemo	284	221	162	0	0	0	0	0	0	0	0

—o— Nivo + Ipi (events: 163/300), median and 95% CI: 9.33 (7.56, 12.52)
- - + - - Chemo (events: 77/284), median and 95% CI: N.A. (N.A., N.A.)
Hazard Ratio (Nivo + Ipi vs Chemo) and 95% CI: 1.744 (1.312, 2.319)

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
Hazard ratio computed using a stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ebr2252-batch1.sas 07DEC2020:11:09:40

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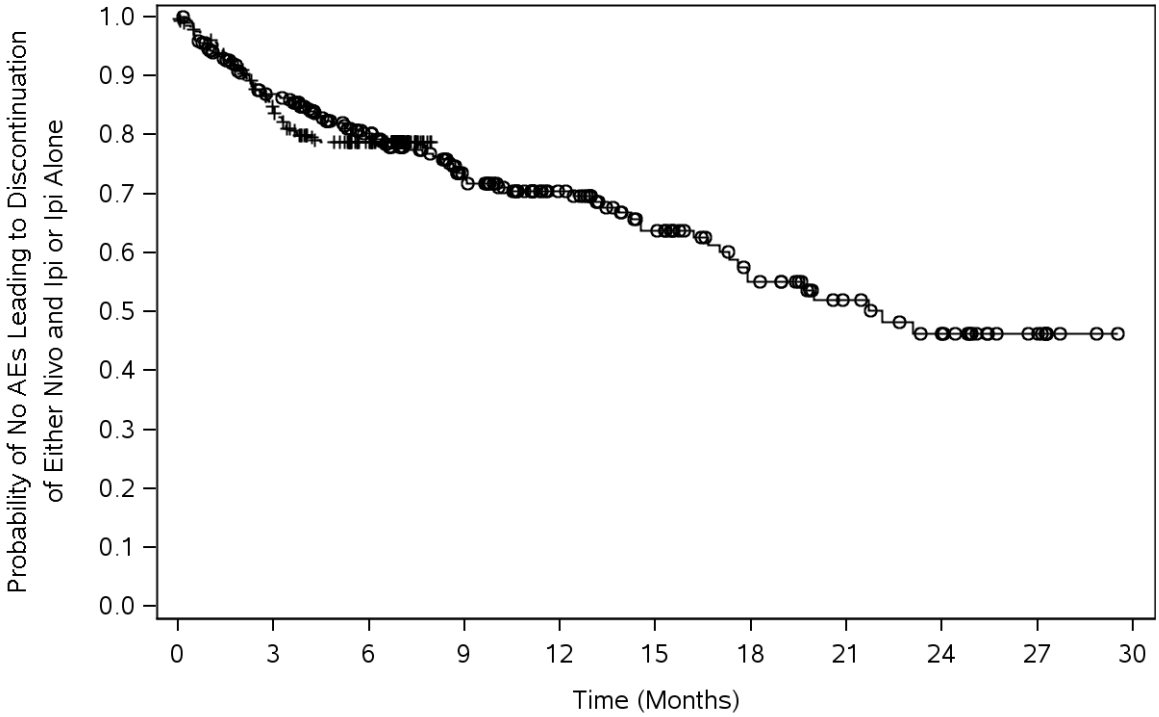
Figure 100.1:
Kaplan-Meier Plot of Time to any - AEs Leading to Discontinuation of Either Nivo and Ipi or Ipi Alone - Excluding Progression Terms - All Treated Subjects



Number of Subjects at Risk

Nivo + Ipi	300	243	177	121	87	62	43	30	21	10	0
Chemo	284	227	174	0	0	0	0	0	0	0	0

—o— Nivo + Ipi (events: 92/300), median and 95% CI: 22.11 (17.58, N.A.)
- -+- - Chemo (events: 58/284), median and 95% CI: N.A. (N.A., N.A.)
Hazard Ratio (Nivo + Ipi vs Chemo) and 95% CI: 0.986 (0.687, 1.413)

April 2020 DBL.
Includes events reported between first dose and 100 days after last dose of study therapy.
Hazard ratio computed using a stratified Cox proportional hazard model.
Symbols represent censored observations.
Program Source: /opt/zfs001/prd/bms214671/stats/market/prog/figures
Program Name: rg-ae-ebr2252-batch1.sas 07DEC2020:11:08:21

Anhang 4-G 6: Details zur Operationalisierung der Unerwünschte Ereignisse von besonderem Interesse (AESI)

Anhang 4-G 6.1: Definition von spezifischen immunvermittelten UE (imUE)

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Immune-Mediated Adverse Events Definition

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

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/kms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:35

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Immune-Mediated Adverse Events Definition

Category	Preferred Terms
HEPATITIS	Immune-mediated hepatitis
	Transaminases increased
HYPERSENSITIVITY	Anaphylactic reaction
	Anaphylactic shock
	Hypersensitivity
	Infusion related hypersensitivity reaction
	Infusion related reaction
HYPERTHYROIDISM	Basedow's disease
	Hyperthyroidism
	Primary hyperthyroidism
HYPOPHYSITIS	Hypophysitis
	Hypopituitarism
	Lymphocytic hypophysitis
HYPOTHYROIDISM	Autoimmune hypothyroidism
	Hypothyroidism
	Immune-mediated hypothyroidism
	Primary hypothyroidism
HYPOTHYROIDISM/THYROIDITIS	Atrophic thyroiditis
	Autoimmune hypothyroidism
	Autoimmune thyroiditis
	Hypothyroidism
	Immune-mediated hypothyroidism
	Immune-mediated thyroiditis
	Primary hypothyroidism
	Silent thyroiditis
	Thyroiditis
	Thyroiditis acute
NEPHRITIS AND RENAL DYSFUNCTION	Acute kidney injury
	Autoimmune nephritis
	Blood creatinine increased

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/bms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:35

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Immune-Mediated Adverse Events Definition

Category	Preferred Terms
NEPHRITIS AND RENAL DYSFUNCTION	Creatinine renal clearance decreased
	End stage renal disease
	Glomerulonephritis rapidly progressive
	Hypercreatininaemia
	Immune-mediated nephritis
	Nephritis
	Nephritis allergic
	Paraneoplastic glomerulonephritis
	Renal failure
	Renal tubular necrosis
	Subacute kidney injury
	Tubulointerstitial nephritis
PNEUMONITIS	Hypersensitivity pneumonitis
	Idiopathic interstitial pneumonia
	Immune-mediated pneumonitis
	Interstitial lung disease
	Pneumonitis
RASH	Autoimmune dermatitis
	Dermatitis
	Dermatitis acneiform
	Dermatitis allergic
	Dermatitis atopic
	Dermatitis exfoliative
	Drug eruption
	Erythema multiforme
	Erythrodermic atopic dermatitis
	Exfoliative rash
	Fixed eruption
	Immune-mediated dermatitis
	Mucocutaneous disorder
	Mucosa vesicle
	Nodular rash
	Pemphigoid
	Pemphigus

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/bms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:35

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Immune-Mediated Adverse Events Definition

Category	Preferred Terms
RASH	Pustule
	Rash
	Rash erythematous
	Rash macular
	Rash maculo-papular
	Rash morbilliform
	Rash papular
	Rash pruritic
	Rash pustular
	Rash vesicular
	Scrotal rash
	Stevens-Johnson syndrome
	Toxic epidermal necrolysis
	Toxic skin eruption
	Urticarial dermatitis
THYROIDITIS	Atrophic thyroiditis
	Autoimmune thyroiditis
	Immune-mediated thyroiditis
	Silent thyroiditis
	Thyroiditis
	Thyroiditis acute

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/bms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:35

Anhang 4-G 6.2: Definition von spezifischen UE (select UE)

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Select Adverse Events Definition

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

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/bms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:30

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Select Adverse Events Definition

Category	Subcategory	Preferred Terms
ENDOCRINE ADVERSE EVENT	THYROID DISORDER	Thyroid function test abnormal
		Thyroid hormones decreased
		Thyroid hormones increased
		Thyroiditis
		Thyroiditis acute
		Thyroxine decreased
		Thyroxine free decreased
		Thyroxine free increased
		Thyroxine increased
		Tri-iodothyronine uptake increased
GASTROINTESTINAL ADVERSE EVENT		Autoimmune colitis
		Autoimmune enteropathy
		Colitis
		Colitis ulcerative
		Diarrhoea
		Duodenal perforation
		Enteritis
		Enterocolitis
		Enterocolitis haemorrhagic
		Frequent bowel movements
		Gastrointestinal perforation
		Immune-mediated enterocolitis
		Lower gastrointestinal perforation
		Ulcerative duodenitis
		Upper gastrointestinal perforation
HEPATIC ADVERSE EVENT		Acute hepatic failure
		Acute on chronic liver failure
		Alanine aminotransferase increased
		Aspartate aminotransferase increased
		Autoimmune hepatitis
		Biliary cirrhosis
		Bilirubin conjugated decreased
		Bilirubin conjugated increased
		Blood alkaline phosphatase increased

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/bms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:30

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Select Adverse Events Definition

Category	Subcategory	Preferred Terms
HEPATIC ADVERSE EVENT		Blood bilirubin increased
		Cholangitis
		Drug-induced liver injury
		Gamma-glutamyltransferase increased
		Hepatic enzyme increased
		Hepatic failure
		Hepatitis
		Hepatitis acute
		Hepatotoxicity
		Hyperbilirubinaemia
		Immune-mediated hepatitis
		Liver disorder
		Liver function test abnormal
		Liver function test increased
		Liver injury
		Transaminases increased
HYPERSENSITIVITY/INFUSION REACTION		Anaphylactic reaction
		Anaphylactic shock
		Bronchospasm
		Hypersensitivity
		Infusion related hypersensitivity reaction
		Infusion related reaction
PULMONARY ADVERSE EVENT		Acute respiratory distress syndrome
		Acute respiratory failure
		Autoimmune lung disease
		Hypersensitivity pneumonitis
		Idiopathic interstitial pneumonia
		Immune-mediated pneumonitis
		Interstitial lung disease
		Lung infiltration
		Pneumonitis
RENAL ADVERSE EVENT		Acute kidney injury
		Autoimmune nephritis

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/bms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:30

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Select Adverse Events Definition

Category	Subcategory	Preferred Terms
RENAL ADVERSE EVENT		Blood creatinine increased
		Blood urea increased
		Creatinine renal clearance decreased
		End stage renal disease
		Glomerulonephritis rapidly progressive
		Hypercreatininaemia
		Immune-mediated nephritis
		Nephritis
		Nephritis allergic
		Paraneoplastic glomerulonephritis
		Renal failure
		Renal tubular necrosis
		Subacute kidney injury
		Tubulointerstitial nephritis
		Urine output decreased
SKIN ADVERSE EVENT		Anal eczema
		Autoimmune dermatitis
		Blister
		Dermatitis
		Dermatitis acneiform
		Dermatitis allergic
		Dermatitis atopic
		Dermatitis exfoliative
		Drug eruption
		Eczema
		Enanthema
		Erythema
		Erythema multiforme
		Erythrodermic atopic dermatitis
		Exfoliative rash
		Fixed eruption
		Guttate psoriasis
		Immune-mediated dermatitis
		Mucocutaneous disorder
		Mucosa vesicle

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/kms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:30

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Select Adverse Events Definition

Category	Subcategory	Preferred Terms
SKIN ADVERSE EVENT		Nodular rash
		Palmar-plantar erythrodysaesthesia syndrome
		Pemphigoid
		Pemphigus
		Photosensitivity reaction
		Pruritus
		Pruritus allergic
		Psoriasis
		Pustular psoriasis
		Pustule
		Rash
		Rash erythematous
		Rash macular
		Rash maculo-papular
		Rash morbilliform
		Rash papular
		Rash pruritic
		Rash pustular
		Rash vesicular
		SJS-TEN overlap
		Scrotal eczema
		Scrotal rash
		Skin exfoliation
		Skin hypopigmentation
		Skin irritation
		Stevens-Johnson syndrome
		Toxic epidermal necrolysis
		Toxic skin eruption
		Urticaria
		Urticarial dermatitis
		Vitiligo
		Vulval eczema

MedDRA Version: 22.1
Program Source: /opt/zfs001/prd/bms242187/stats/primary/prog/listings/rl-ae-slaedef-sas.sas 18MAY2020:18:13:30

Anhang 4-G 6.3: Definition von weiteren UE von besonderem Interesse (OESI)

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Other Events of Special Interest Definition

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

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Other Events of Special Interest Definition

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

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Other Events of Special Interest Definition

Category	Preferred Terms
UVEITIS EVENT	Cyclitis
	Immune recovery uveitis
	Immune-mediated uveitis
	Iridocyclitis
	Iritis
	Keratouveitis
	Uveitis
	Vogt-Koyanagi-Harada disease

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