

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Nivolumab (OPDIVO®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 ZB

Anhang 4-G

*Nivolumab in Kombination mit Ipilimumab zur
Erstlinienbehandlung des nicht resezierbaren oder
fortgeschrittenen hepatozellulären Karzinoms (HCC)*

Ergänzende Analysen

Stand: 12.06.2025

Protocol: CA2099DW

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Table 14.1.4.7
Baseline Disease Characteristics Summary - Extended
All Randomized Subjects

	Number of Subjects (%)		
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Total N = 668
ETIOLOGY PER CRF (%)			
HEV	114 (34.0)	115 (34.5)	229 (34.3)
HCV	90 (26.9)	96 (28.8)	186 (27.8)
UNINFECTED	124 (37.0)	119 (35.7)	243 (36.4)
HBV/HCV	7 (2.1)	3 (0.9)	10 (1.5)

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Table 14.1.5.15
Subsequent Cancer Therapy Summary
All Randomized Subjects

	Number of Subjects (%)	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
SUBJECTS WITH ANY SUBSEQUENT THERAPY (%) (1)	151 (45.1)	185 (55.6)
SUBJECTS WHO RECEIVED SUBSEQUENT RADIOTHERAPY (%)	21 (6.3)	25 (7.5)
SUBJECTS WHO RECEIVED SUBSEQUENT SURGERY (%)	12 (3.6)	6 (1.8)
SUBJECTS WHO RECEIVED SUBSEQUENT NON-SYSTEMIC FOR HCC (LOCAL ONLY) (%)	29 (8.7)	27 (8.1)
SUBJECTS WHO RECEIVED SUBSEQUENT SYSTEMIC THERAPY (%)	128 (38.2)	172 (51.7)
ANTI-PD1 OR ANTI-PDL1	10 (3.0)	47 (14.1)
ATEZOLIZUMAB	1 (0.3)	1 (0.3)
DURVALUMAB	0	3 (0.9)
INCB 086550	0	1 (0.3)
NIVOLUMAB	9 (2.7)	35 (10.5)
PEMBROLIZUMAB	0	5 (1.5)
SINTILIMAB	0	1 (0.3)
TISLELIZUMAB	0	1 (0.3)
COMBO ANTI-CTLA4 + ANTI-PD1 + VEGF OR COMBO ANTI-CTLA4 + ANTI-PDL1 + VEGF	2 (0.6)	3 (0.9)
BEVACIZUMAB; IPILIMUMAB; NIVOLUMAB	0	1 (0.3)
CABOZANTINIB; IPILIMUMAB; PEMBROLIZUMAB	0	1 (0.3)
IPILIMUMAB; LENVATINIB; NIVOLUMAB	0	1 (0.3)
IPILIMUMAB; NIVOLUMAB; SORAFENIB TOSILATE	1 (0.3)	0
IPILIMUMAB; PEMBROLIZUMAB; RAMUCIRUMAB	1 (0.3)	0
COMBO ANTI-CTLA4 + ANTI-PD1 OR COMBO ANTI-CTLA4 + ANTI-PDL1	2 (0.6)	10 (3.0)
DURVALUMAB; TREMELIMUMAB	2 (0.6)	4 (1.2)
IPILIMUMAB; NIVOLUMAB	0	6 (1.8)

(1) Subject may have received more than one type of subsequent therapy. Subsequent therapy was defined as therapy started on or after first dosing date (randomization date if subject never treated).

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-ct-fuththerapy.sas

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Table 14.1.5.15
Subsequent Cancer Therapy Summary
All Randomized Subjects

	Number of Subjects (%)	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
COMBO ANTI-PD1 + OTHER SYSTEMIC ANTICANCER THERAPY OR COMBO ANTI-PDL1 + OTHER SYSTEMIC ANTICANCER THERAPY	3 (0.9)	0
ANTINEOPLASTIC MONOCLONAL ANTIBODIES;TISLELIZUMAB	1 (0.3)	0
CEMIPLIMAB;SAR 439459	1 (0.3)	0
DOCETAXEL;FLUOROURACIL;NIVOLUMAB;OXALIPLATIN	1 (0.3)	0
OTHER MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES;PEMBROLIZUMAB	1 (0.3)	0
COMBO ANTI-PD1 + VEGF OR COMBO ANTI-PDL1 + VEGF	29 (8.7)	67 (20.1)
ATEZOLIZUMAB;BEVACIZUMAB	20 (6.0)	64 (19.2)
ATEZOLIZUMAB;LENVATINIB MESILATE	1 (0.3)	0
BEVACIZUMAB;SINTILIMAB	1 (0.3)	0
CABOZANTINIB;PEMBROLIZUMAB	1 (0.3)	0
CAMRELIZUMAB;LENVATINIB	1 (0.3)	0
CAMRELIZUMAB;SORAFENIB TOSILATE	0	1 (0.3)
LENVATINIB MESILATE;SINTILIMAB	1 (0.3)	0
LENVATINIB MESILATE;TISLELIZUMAB	1 (0.3)	0
LENVATINIB;NIVOLUMAB	0	1 (0.3)
LENVATINIB;PEMBROLIZUMAB	2 (0.6)	0
NIVOLUMAB;REGORAFENIB	0	1 (0.3)
PEMBROLIZUMAB;REGORAFENIB	6 (1.8)	1 (0.3)
PEMBROLIZUMAB;SORAFENIB	0	1 (0.3)
REGORAFENIB;TISLELIZUMAB	1 (0.3)	0
SINTILIMAB;SORAFENIB TOSILATE	1 (0.3)	0
SORAFENIB;TISLELIZUMAB	1 (0.3)	0
COMBO PD1/PDL1 AND LAG3	0	12 (3.6)
NIVOLUMAB;RELATLIMAB	0	8 (2.4)
TEBOTELIMAB	0	4 (1.2)
INVESTIGATIONAL ANTINEOPLASTIC AGENTS	1 (0.3)	3 (0.9)

(1) Subject may have received more than one type of subsequent therapy. Subsequent therapy was defined as therapy started on or after first dosing date (randomization date if subject never treated).

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-ct-fuththerapy.sas

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Table 14.1.5.15
Subsequent Cancer Therapy Summary
All Randomized Subjects

	Number of Subjects (%)	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
INVESTIGATIONAL ANTINEOPLASTIC DRUGS	1 (0.3)	1 (0.3)
INVESTIGATIONAL DRUG	0	2 (0.6)
PLATINUM COMPOUNDS	4 (1.2)	3 (0.9)
CISPLATIN;DOXORUBICIN HYDROCHLORIDE	1 (0.3)	0
CISPLATIN;GEMCITABINE	0	1 (0.3)
FLUOROURACIL;FLUOROURACIL;FOLINIC ACID;OXALIPLATIN	1 (0.3)	0
FLUOROURACIL;OXALIPLATIN	1 (0.3)	0
GEMCITABINE HYDROCHLORIDE;OXALIPLATIN	1 (0.3)	0
GEMCITABINE;OXALIPLATIN	0	2 (0.6)
VEGFR TARGETED THERAPY	95 (28.4)	99 (29.7)
BEVACIZUMAB	0	1 (0.3)
CABOZANTINIB	8 (2.4)	27 (8.1)
CABOZANTINIB S-MALATE	1 (0.3)	6 (1.8)
CATEQUENTINIB HYDROCHLORIDE	1 (0.3)	0
LENVATINIB	37 (11.0)	13 (3.9)
LENVATINIB MESILATE	10 (3.0)	9 (2.7)
RAMUCIRUMAB	3 (0.9)	3 (0.9)
REGORAFENIB	9 (2.7)	26 (7.8)
SORAFENIB	40 (11.9)	43 (12.9)
SORAFENIB TOSILATE	8 (2.4)	9 (2.7)
OTHER SYSTEMIC ANTICANCER THERAPY	1 (0.3)	5 (1.5)
CAPECITABINE	0	1 (0.3)
CAPECITABINE;OXALIPLATIN;RAMUCIRUMAB	0	1 (0.3)
CAPECITABINE;THALIDOMIDE	0	1 (0.3)
EPIRUBICIN HYDROCHLORIDE;ETOPOSIDE	1 (0.3)	0
LAROTRECTINIB	0	1 (0.3)
TRAMETES ROBINIOPHILA	0	1 (0.3)

(1) Subject may have received more than one type of subsequent therapy. Subsequent therapy was defined as therapy started on or after first dosing date (randomization date if subject never treated).

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Table 14.7.1.2
EQ-5D-3L Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
BASELINE	332/335 (99.1)	331/333 (99.4)	332/335 (99.1)	330/333 (99.1)
ON-TREATMENT				
WEEK 4	274/306 (89.5)	288/307 (93.8)	279/306 (91.2)	288/307 (93.8)
WEEK 7	234/267 (87.6)	272/290 (93.8)	235/267 (88.0)	271/290 (93.4)
WEEK 10	198/228 (86.8)	239/269 (88.8)	197/228 (86.4)	240/269 (89.2)
WEEK 13	183/207 (88.4)	236/246 (95.9)	183/207 (88.4)	236/246 (95.9)
WEEK 17	170/186 (91.4)	209/230 (90.9)	170/186 (91.4)	209/230 (90.9)
WEEK 21	159/173 (91.9)	179/201 (89.1)	160/173 (92.5)	178/201 (88.6)
WEEK 25	146/159 (91.8)	167/182 (91.8)	146/159 (91.8)	166/182 (91.2)
WEEK 29	142/150 (94.7)	159/167 (95.2)	142/150 (94.7)	160/167 (95.8)
WEEK 33	132/139 (95.0)	138/151 (91.4)	132/139 (95.0)	138/151 (91.4)
WEEK 37	121/132 (91.7)	131/142 (92.3)	121/132 (91.7)	132/142 (93.0)
WEEK 41	115/122 (94.3)	113/124 (91.1)	116/122 (95.1)	112/124 (90.3)
WEEK 45	112/118 (94.9)	105/113 (92.9)	112/118 (94.9)	105/113 (92.9)
WEEK 49	104/111 (93.7)	95/107 (88.8)	106/111 (95.5)	95/107 (88.8)

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have EQ-5D-3L assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Table 14.7.1.2
EQ-5D-3L Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 53	96/105 (91.4)	90/97 (92.8)	96/105 (91.4)	90/97 (92.8)
WEEK 57	94/100 (94.0)	89/93 (95.7)	94/100 (94.0)	89/93 (95.7)
WEEK 61	88/94 (93.6)	78/88 (88.6)	88/94 (93.6)	77/88 (87.5)
WEEK 65	86/89 (96.6)	63/71 (88.7)	86/89 (96.6)	63/71 (88.7)
WEEK 69	76/84 (90.5)	56/64 (87.5)	75/84 (89.3)	58/64 (90.6)
WEEK 73	73/78 (93.6)	53/55 (96.4)	73/78 (93.6)	53/55 (96.4)
WEEK 77	72/76 (94.7)	39/43 (90.7)	72/76 (94.7)	39/43 (90.7)
WEEK 81	72/76 (94.7)	36/39 (92.3)	72/76 (94.7)	36/39 (92.3)
WEEK 85	66/71 (93.0)	33/34 (97.1)	66/71 (93.0)	33/34 (97.1)
WEEK 89	63/67 (94.0)	25/34 (73.5)	63/67 (94.0)	25/34 (73.5)
WEEK 93	65/66 (98.5)	27/29 (93.1)	65/66 (98.5)	27/29 (93.1)
WEEK 97	63/66 (95.5)	24/27 (88.9)	63/66 (95.5)	24/27 (88.9)
WEEK 101	59/62 (95.2)	20/23 (87.0)	58/62 (93.5)	20/23 (87.0)
WEEK 105	38/39 (97.4)	22/22 (100.0)	38/39 (97.4)	22/22 (100.0)
WEEK 109	1/1 (100.0)	20/21 (95.2)	1/1 (100.0)	20/21 (95.2)

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have EQ-5D-3L assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Table 14.7.1.2
EQ-5D-3L Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 113	N.A.	17/19 (89.5)	N.A.	17/19 (89.5)
WEEK 117	N.A.	17/18 (94.4)	N.A.	18/18 (100.0)
WEEK 121	N.A.	16/16 (100.0)	N.A.	16/16 (100.0)
WEEK 125	N.A.	12/15 (80.0)	N.A.	12/15 (80.0)
WEEK 129	N.A.	13/14 (92.9)	N.A.	13/14 (92.9)
WEEK 133	N.A.	9/13 (69.2)	N.A.	9/13 (69.2)
WEEK 137	N.A.	10/10 (100.0)	N.A.	10/10 (100.0)
WEEK 141	N.A.	8/8 (100.0)	N.A.	8/8 (100.0)
WEEK 145	N.A.	7/7 (100.0)	N.A.	7/7 (100.0)
WEEK 149	N.A.	5/5 (100.0)	N.A.	5/5 (100.0)
WEEK 153	N.A.	5/5 (100.0)	N.A.	5/5 (100.0)
WEEK 157	N.A.	3/3 (100.0)	N.A.	3/3 (100.0)
WEEK 161	N.A.	3/3 (100.0)	N.A.	3/3 (100.0)
WEEK 165	N.A.	1/1 (100.0)	N.A.	1/1 (100.0)
WEEK 169	N.A.	0/1	N.A.	0/1

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have EQ-5D-3L assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Table 14.7.1.2
EQ-5D-3L Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 173	N.A.	0/1	N.A.	0/1
WEEK 177	N.A.	1/1 (100.0)	N.A.	1/1 (100.0)
WEEK 181	N.A.	1/1 (100.0)	N.A.	1/1 (100.0)
WEEK 185	N.A.	1/1 (100.0)	N.A.	1/1 (100.0)
WEEK 189	N.A.	0/1	N.A.	0/1
WEEK 193	N.A.	1/1 (100.0)	N.A.	1/1 (100.0)
WEEK 197	N.A.	1/1 (100.0)	N.A.	1/1 (100.0)
FOLLOW-UP				
FOLLOW-UP 1	214/286 (74.8)	211/275 (76.7)	213/286 (74.5)	211/275 (76.7)
FOLLOW-UP 2	157/242 (64.9)	124/217 (57.1)	157/242 (64.9)	123/217 (56.7)
SURVIVAL FOLLOW-UP 1	104/199 (52.3)	71/165 (43.0)	104/199 (52.3)	71/165 (43.0)
SURVIVAL FOLLOW-UP 2	87/157 (55.4)	64/144 (44.4)	87/157 (55.4)	64/144 (44.4)
SURVIVAL FOLLOW-UP 3	73/130 (56.2)	48/115 (41.7)	72/130 (55.4)	47/115 (40.9)
SURVIVAL FOLLOW-UP 4	62/103 (60.2)	35/92 (38.0)	62/103 (60.2)	35/92 (38.0)
SURVIVAL FOLLOW-UP 5	46/85 (54.1)	25/71 (35.2)	46/85 (54.1)	25/71 (35.2)

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have EQ-5D-3L assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Table 14.7.1.2
EQ-5D-3L Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
SURVIVAL FOLLOW-UP 6	40/74 (54.1)	19/53 (35.8)	40/74 (54.1)	19/53 (35.8)
SURVIVAL FOLLOW-UP 7	32/65 (49.2)	9/31 (29.0)	32/65 (49.2)	9/31 (29.0)
SURVIVAL FOLLOW-UP 8	25/47 (53.2)	6/24 (25.0)	25/47 (53.2)	6/24 (25.0)
SURVIVAL FOLLOW-UP 9	16/34 (47.1)	0/12	16/34 (47.1)	0/12
SURVIVAL FOLLOW-UP 10	8/18 (44.4)	1/6 (16.7)	8/18 (44.4)	1/6 (16.7)
SURVIVAL FOLLOW-UP 11	1/9 (11.1)	0/3	1/9 (11.1)	0/3
SURVIVAL FOLLOW-UP 12	1/5 (20.0)	0/1	1/5 (20.0)	0/1
SURVIVAL FOLLOW-UP 13	0/2	N.A.	0/2	N.A.

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have EQ-5D-3L assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Table 14.7.1.1
EQ-5D-3L Questionnaire Available Data Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
BASELINE	332/335 (99.1)	331/333 (99.4)	332/335 (99.1)	330/333 (99.1)
ON-TREATMENT				
WEEK 4	274/335 (81.8)	288/333 (86.5)	279/335 (83.3)	288/333 (86.5)
WEEK 7	234/335 (69.9)	272/333 (81.7)	235/335 (70.1)	271/333 (81.4)
WEEK 10	198/335 (59.1)	239/333 (71.8)	197/335 (58.8)	240/333 (72.1)
WEEK 13	183/335 (54.6)	236/333 (70.9)	183/335 (54.6)	236/333 (70.9)
WEEK 17	170/335 (50.7)	209/333 (62.8)	170/335 (50.7)	209/333 (62.8)
WEEK 21	159/335 (47.5)	179/333 (53.8)	160/335 (47.8)	178/333 (53.5)
WEEK 25	146/335 (43.6)	167/333 (50.2)	146/335 (43.6)	166/333 (49.8)
WEEK 29	142/335 (42.4)	159/333 (47.7)	142/335 (42.4)	160/333 (48.0)
WEEK 33	132/335 (39.4)	138/333 (41.4)	132/335 (39.4)	138/333 (41.4)
WEEK 37	121/335 (36.1)	131/333 (39.3)	121/335 (36.1)	132/333 (39.6)
WEEK 41	115/335 (34.3)	113/333 (33.9)	116/335 (34.6)	112/333 (33.6)
WEEK 45	112/335 (33.4)	105/333 (31.5)	112/335 (33.4)	105/333 (31.5)
WEEK 49	104/335 (31.0)	95/333 (28.5)	106/335 (31.6)	95/333 (28.5)

N.A.: Not Assessed.

Available Data Rate=number of subjects who filled a valid questionnaire/number of randomized subjects (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Table 14.7.1.1
EQ-5D-3L Questionnaire Available Data Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 53	96/335 (28.7)	90/333 (27.0)	96/335 (28.7)	90/333 (27.0)
WEEK 57	94/335 (28.1)	89/333 (26.7)	94/335 (28.1)	89/333 (26.7)
WEEK 61	88/335 (26.3)	78/333 (23.4)	88/335 (26.3)	77/333 (23.1)
WEEK 65	86/335 (25.7)	63/333 (18.9)	86/335 (25.7)	63/333 (18.9)
WEEK 69	76/335 (22.7)	56/333 (16.8)	75/335 (22.4)	58/333 (17.4)
WEEK 73	73/335 (21.8)	53/333 (15.9)	73/335 (21.8)	53/333 (15.9)
WEEK 77	72/335 (21.5)	39/333 (11.7)	72/335 (21.5)	39/333 (11.7)
WEEK 81	72/335 (21.5)	36/333 (10.8)	72/335 (21.5)	36/333 (10.8)
WEEK 85	66/335 (19.7)	33/333 (9.9)	66/335 (19.7)	33/333 (9.9)
WEEK 89	63/335 (18.8)	25/333 (7.5)	63/335 (18.8)	25/333 (7.5)
WEEK 93	65/335 (19.4)	27/333 (8.1)	65/335 (19.4)	27/333 (8.1)
WEEK 97	63/335 (18.8)	24/333 (7.2)	63/335 (18.8)	24/333 (7.2)
WEEK 101	59/335 (17.6)	20/333 (6.0)	58/335 (17.3)	20/333 (6.0)
WEEK 105	38/335 (11.3)	22/333 (6.6)	38/335 (11.3)	22/333 (6.6)
WEEK 109	1/335 (0.3)	20/333 (6.0)	1/335 (0.3)	20/333 (6.0)

N.A.: Not Assessed.

Available Data Rate=number of subjects who filled a valid questionnaire/number of randomized subjects (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Table 14.7.1.1
EQ-5D-3L Questionnaire Available Data Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 113	N.A.	17/333 (5.1)	N.A.	17/333 (5.1)
WEEK 117	N.A.	17/333 (5.1)	N.A.	18/333 (5.4)
WEEK 121	N.A.	16/333 (4.8)	N.A.	16/333 (4.8)
WEEK 125	N.A.	12/333 (3.6)	N.A.	12/333 (3.6)
WEEK 129	N.A.	13/333 (3.9)	N.A.	13/333 (3.9)
WEEK 133	N.A.	9/333 (2.7)	N.A.	9/333 (2.7)
WEEK 137	N.A.	10/333 (3.0)	N.A.	10/333 (3.0)
WEEK 141	N.A.	8/333 (2.4)	N.A.	8/333 (2.4)
WEEK 145	N.A.	7/333 (2.1)	N.A.	7/333 (2.1)
WEEK 149	N.A.	5/333 (1.5)	N.A.	5/333 (1.5)
WEEK 153	N.A.	5/333 (1.5)	N.A.	5/333 (1.5)
WEEK 157	N.A.	3/333 (0.9)	N.A.	3/333 (0.9)
WEEK 161	N.A.	3/333 (0.9)	N.A.	3/333 (0.9)
WEEK 165	N.A.	1/333 (0.3)	N.A.	1/333 (0.3)
WEEK 169	N.A.	0/333	N.A.	0/333

N.A.: Not Assessed.

Available Data Rate=number of subjects who filled a valid questionnaire/number of randomized subjects (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Protocol: CA2099DW

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Table 14.7.1.1
EQ-5D-3L Questionnaire Available Data Rate
All Randomized Subjects

Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 173	N.A.	0/333	N.A.	0/333
WEEK 177	N.A.	1/333 (0.3)	N.A.	1/333 (0.3)
WEEK 181	N.A.	1/333 (0.3)	N.A.	1/333 (0.3)
WEEK 185	N.A.	1/333 (0.3)	N.A.	1/333 (0.3)
WEEK 189	N.A.	0/333	N.A.	0/333
WEEK 193	N.A.	1/333 (0.3)	N.A.	1/333 (0.3)
WEEK 197	N.A.	1/333 (0.3)	N.A.	1/333 (0.3)
FOLLOW-UP				
FOLLOW-UP 1	214/335 (63.9)	211/333 (63.4)	213/335 (63.6)	211/333 (63.4)
FOLLOW-UP 2	157/335 (46.9)	124/333 (37.2)	157/335 (46.9)	123/333 (36.9)
SURVIVAL FOLLOW-UP 1	104/335 (31.0)	71/333 (21.3)	104/335 (31.0)	71/333 (21.3)
SURVIVAL FOLLOW-UP 2	87/335 (26.0)	64/333 (19.2)	87/335 (26.0)	64/333 (19.2)
SURVIVAL FOLLOW-UP 3	73/335 (21.8)	48/333 (14.4)	72/335 (21.5)	47/333 (14.1)
SURVIVAL FOLLOW-UP 4	62/335 (18.5)	35/333 (10.5)	62/335 (18.5)	35/333 (10.5)
SURVIVAL FOLLOW-UP 5	46/335 (13.7)	25/333 (7.5)	46/335 (13.7)	25/333 (7.5)

N.A.: Not Assessed.

Available Data Rate=number of subjects who filled a valid questionnaire/number of randomized subjects (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Protocol: CA2099DW

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Table 14.7.1.1
EQ-5D-3L Questionnaire Available Data Rate
All Randomized Subjects

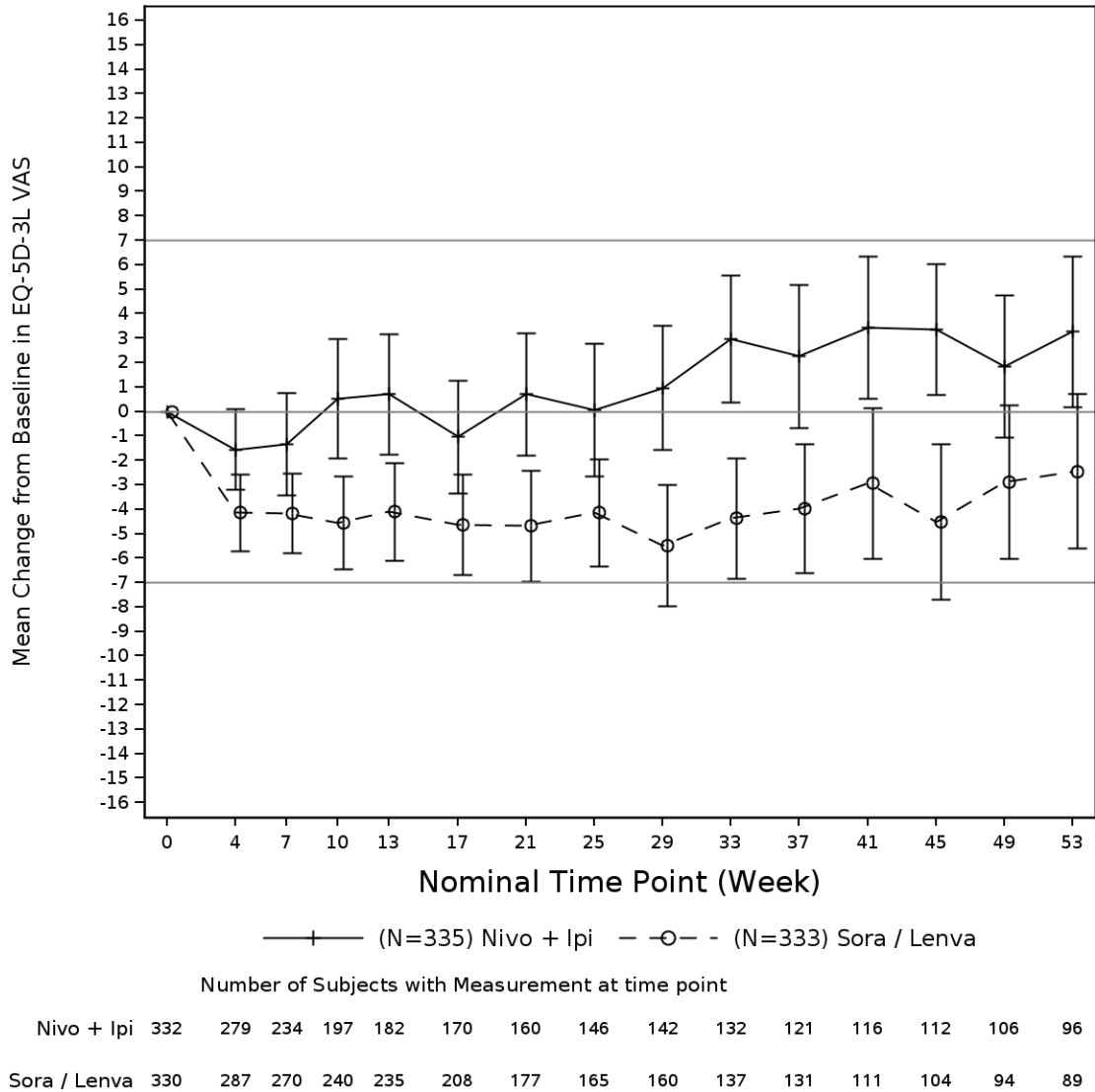
Nominal Timepoint	EQ-5D-3L Descriptive System		EQ-5D-3L VAS	
	Nivo + Ipi N = 335	Sora / Lenva N = 333	Nivo + Ipi N = 335	Sora / Lenva N = 333
SURVIVAL FOLLOW-UP 6	40/335 (11.9)	19/333 (5.7)	40/335 (11.9)	19/333 (5.7)
SURVIVAL FOLLOW-UP 7	32/335 (9.6)	9/333 (2.7)	32/335 (9.6)	9/333 (2.7)
SURVIVAL FOLLOW-UP 8	25/335 (7.5)	6/333 (1.8)	25/335 (7.5)	6/333 (1.8)
SURVIVAL FOLLOW-UP 9	16/335 (4.8)	0/333	16/335 (4.8)	0/333
SURVIVAL FOLLOW-UP 10	8/335 (2.4)	1/333 (0.3)	8/335 (2.4)	1/333 (0.3)
SURVIVAL FOLLOW-UP 11	1/335 (0.3)	0/333	1/335 (0.3)	0/333
SURVIVAL FOLLOW-UP 12	1/335 (0.3)	0/333	1/335 (0.3)	0/333
SURVIVAL FOLLOW-UP 13	0/335	N.A.	0/335	N.A.

N.A.: Not Assessed.
Available Data Rate=number of subjects who filled a valid questionnaire/number of randomized subjects (%)
Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas 20MAR2024:05:22:28

Protocol: CA2099DW

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Figure 14.7.1.1.2:
Mean Changes in Overall Self-Rated Health Status EQ-VAS from Baseline - All Randomized Subjects



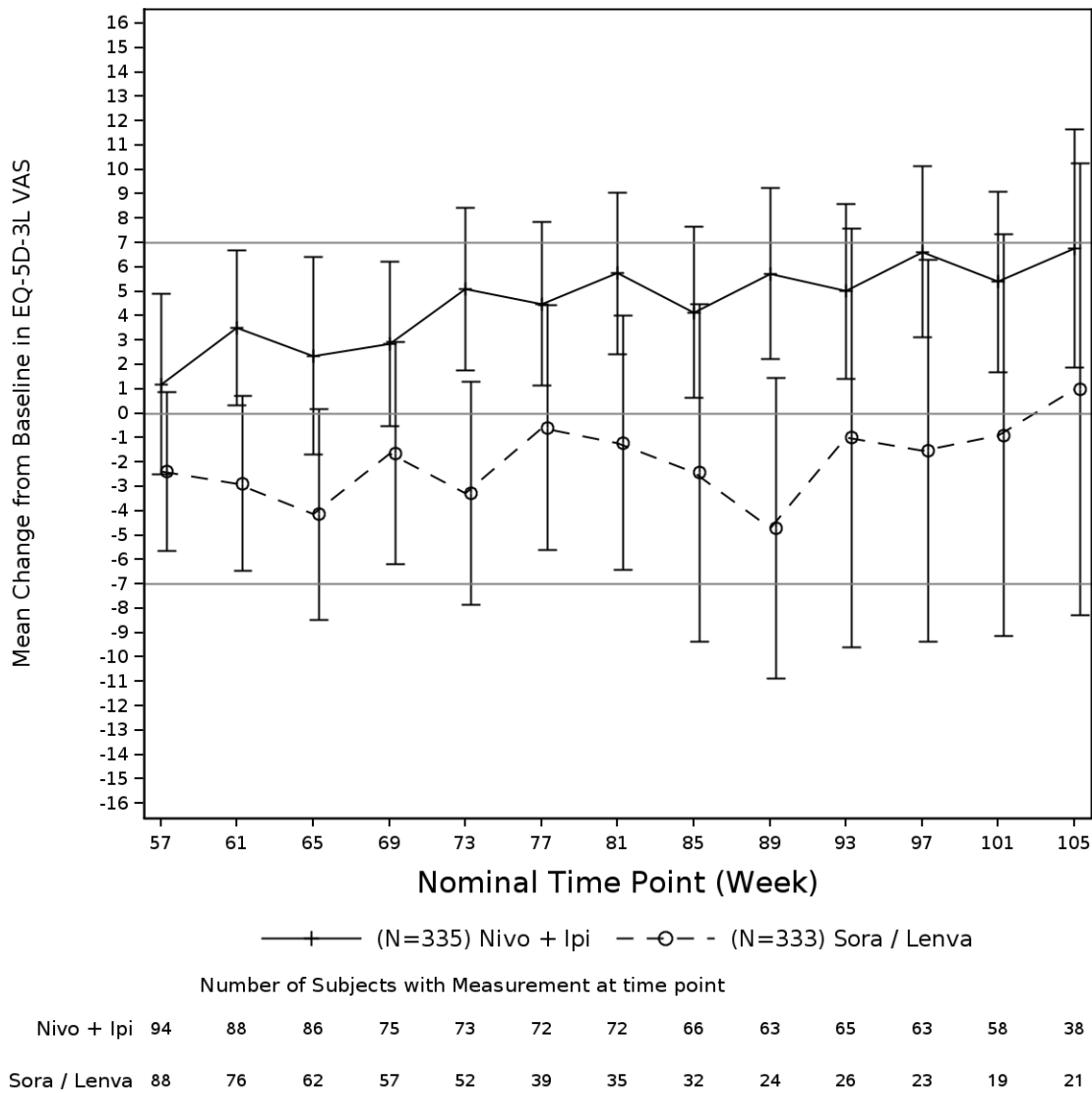
Error bars represent standard error for the mean.
Horizontal reference line indicates a minimally important difference (MID), considered a change of ≥ 7 from baseline.
Only time points where data available for ≥ 5 subjects in each treatment group are plotted.
Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/figures
Program Name: rg-sy-chgbs1.sas
20MAR2024:05:26:38

Protocol: CA2099DW

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Figure 14.7.1.1.2:

Mean Changes in Overall Self-Rated Health Status EQ-VAS from Baseline - All Randomized Subjects



Error bars represent standard error for the mean.

Horizontal reference line indicates a minimally important difference (MID), considered a change of ≥ 7 from baseline.

Only time points where data available for ≥ 5 subjects in each treatment group are plotted.

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/figures

Program Name: rg-sy-chgbsl.sas

20MAR2024:05:26:38

Protocol: CA2099DW

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Table 14.7.2.1
FACT-Hep Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	FACT-Hep	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
BASELINE	332/335 (99.1)	330/333 (99.1)
ON-TREATMENT		
WEEK 4	278/306 (90.8)	291/306 (95.1)
WEEK 7	236/267 (88.4)	274/290 (94.5)
WEEK 10	196/228 (86.0)	243/269 (90.3)
WEEK 13	182/207 (87.9)	238/246 (96.7)
WEEK 17	172/186 (92.5)	208/230 (90.4)
WEEK 21	160/173 (92.5)	179/201 (89.1)
WEEK 25	146/159 (91.8)	168/182 (92.3)
WEEK 29	142/150 (94.7)	160/167 (95.8)
WEEK 33	132/139 (95.0)	140/150 (93.3)
WEEK 37	124/132 (93.9)	132/142 (93.0)
WEEK 41	117/122 (95.9)	114/125 (91.2)
WEEK 45	111/118 (94.1)	106/113 (93.8)
WEEK 49	106/111 (95.5)	97/107 (90.7)

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have FACT-Hep assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

20MAR2024:05:22:43

Protocol: CA2099DW

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Table 14.7.2.1
FACT-Hep Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	FACT-Hep	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 53	94/105 (89.5)	92/97 (94.8)
WEEK 57	93/100 (93.0)	91/93 (97.8)
WEEK 61	87/94 (92.6)	79/88 (89.8)
WEEK 65	86/89 (96.6)	63/71 (88.7)
WEEK 69	76/84 (90.5)	58/64 (90.6)
WEEK 73	74/78 (94.9)	53/55 (96.4)
WEEK 77	73/76 (96.1)	39/43 (90.7)
WEEK 81	73/76 (96.1)	36/39 (92.3)
WEEK 85	68/72 (94.4)	34/34 (100.0)
WEEK 89	63/67 (94.0)	28/34 (82.4)
WEEK 93	64/66 (97.0)	27/29 (93.1)
WEEK 97	63/66 (95.5)	24/27 (88.9)
WEEK 101	59/62 (95.2)	20/23 (87.0)
WEEK 105	38/39 (97.4)	22/22 (100.0)
WEEK 109	1/1 (100.0)	19/21 (90.5)

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have FACT-Hep assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Protocol: CA2099DW

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Table 14.7.2.1
FACT-Hep Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	FACT-Hep	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 113	N.A.	16/19 (84.2)
WEEK 117	N.A.	18/18 (100.0)
WEEK 121	N.A.	16/16 (100.0)
WEEK 125	N.A.	13/15 (86.7)
WEEK 129	N.A.	13/14 (92.9)
WEEK 133	N.A.	9/13 (69.2)
WEEK 137	N.A.	10/10 (100.0)
WEEK 141	N.A.	8/8 (100.0)
WEEK 145	N.A.	7/7 (100.0)
WEEK 149	N.A.	5/5 (100.0)
WEEK 153	N.A.	5/5 (100.0)
WEEK 157	N.A.	3/3 (100.0)
WEEK 161	N.A.	3/3 (100.0)
WEEK 165	N.A.	1/1 (100.0)
WEEK 169	N.A.	0/1

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have FACT-Hep assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

20MAR2024:05:22:43

Protocol: CA2099DW

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Table 14.7.2.1
FACT-Hep Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	FACT-Hep	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
WEEK 173	N.A.	1/1 (100.0)
WEEK 177	N.A.	1/1 (100.0)
WEEK 181	N.A.	1/1 (100.0)
WEEK 185	N.A.	1/1 (100.0)
WEEK 189	N.A.	0/1
WEEK 193	N.A.	1/1 (100.0)
WEEK 197	N.A.	1/1 (100.0)
FOLLOW-UP		
FOLLOW-UP 1	214/285 (75.1)	213/275 (77.5)
FOLLOW-UP 2	152/242 (62.8)	122/217 (56.2)
SURVIVAL FOLLOW-UP 1	96/199 (48.2)	70/165 (42.4)
SURVIVAL FOLLOW-UP 2	82/157 (52.2)	61/144 (42.4)
SURVIVAL FOLLOW-UP 3	68/130 (52.3)	47/115 (40.9)
SURVIVAL FOLLOW-UP 4	55/102 (53.9)	32/92 (34.8)
SURVIVAL FOLLOW-UP 5	44/85 (51.8)	24/71 (33.8)

N.A.: Not Assessed.

Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have FACT-Hep assessment at the designated time point (%)

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas

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Protocol: CA2099DW

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Table 14.7.2.1
FACT-Hep Questionnaire Completion Rate
All Randomized Subjects

Nominal Timepoint	FACT-Hep	
	Nivo + Ipi N = 335	Sora / Lenva N = 333
SURVIVAL FOLLOW-UP 6	40/74 (54.1)	17/52 (32.7)
SURVIVAL FOLLOW-UP 7	30/64 (46.9)	8/31 (25.8)
SURVIVAL FOLLOW-UP 8	25/47 (53.2)	6/24 (25.0)
SURVIVAL FOLLOW-UP 9	16/34 (47.1)	0/12
SURVIVAL FOLLOW-UP 10	8/18 (44.4)	0/5
SURVIVAL FOLLOW-UP 11	1/9 (11.1)	0/3
SURVIVAL FOLLOW-UP 12	1/5 (20.0)	0/1
SURVIVAL FOLLOW-UP 13	0/2	N.A.

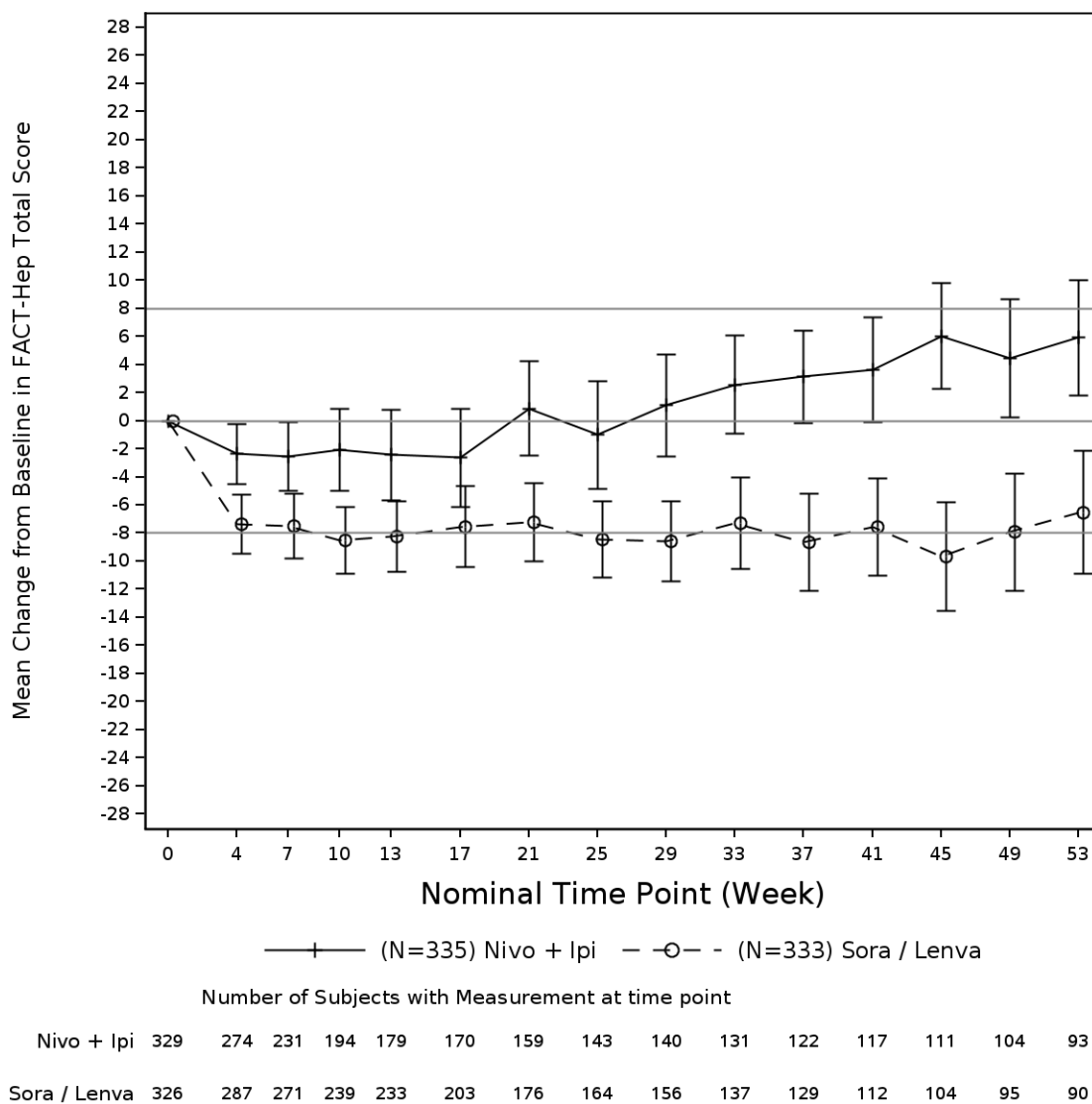
N.A.: Not Assessed.
Completion Rate=number of subjects who filled a valid questionnaire/number of subjects expected to have FACT-Hep assessment at the designated time point (%)
Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/tables/rt-sy-eq5dcompl.sas
20MAR2024:05:22:43

Protocol: CA2099DW

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Figure 14.7.2.1.1:

Mean Changes in FACT-Hep Total Score from Baseline - All Randomized Subjects



Error bars represent standard error for the mean.

Horizontal reference line indicates a minimally important difference (MID), considered a change ≥ 8 points from baseline.

Only time points where data available for ≥ 5 subjects in each treatment group are plotted.

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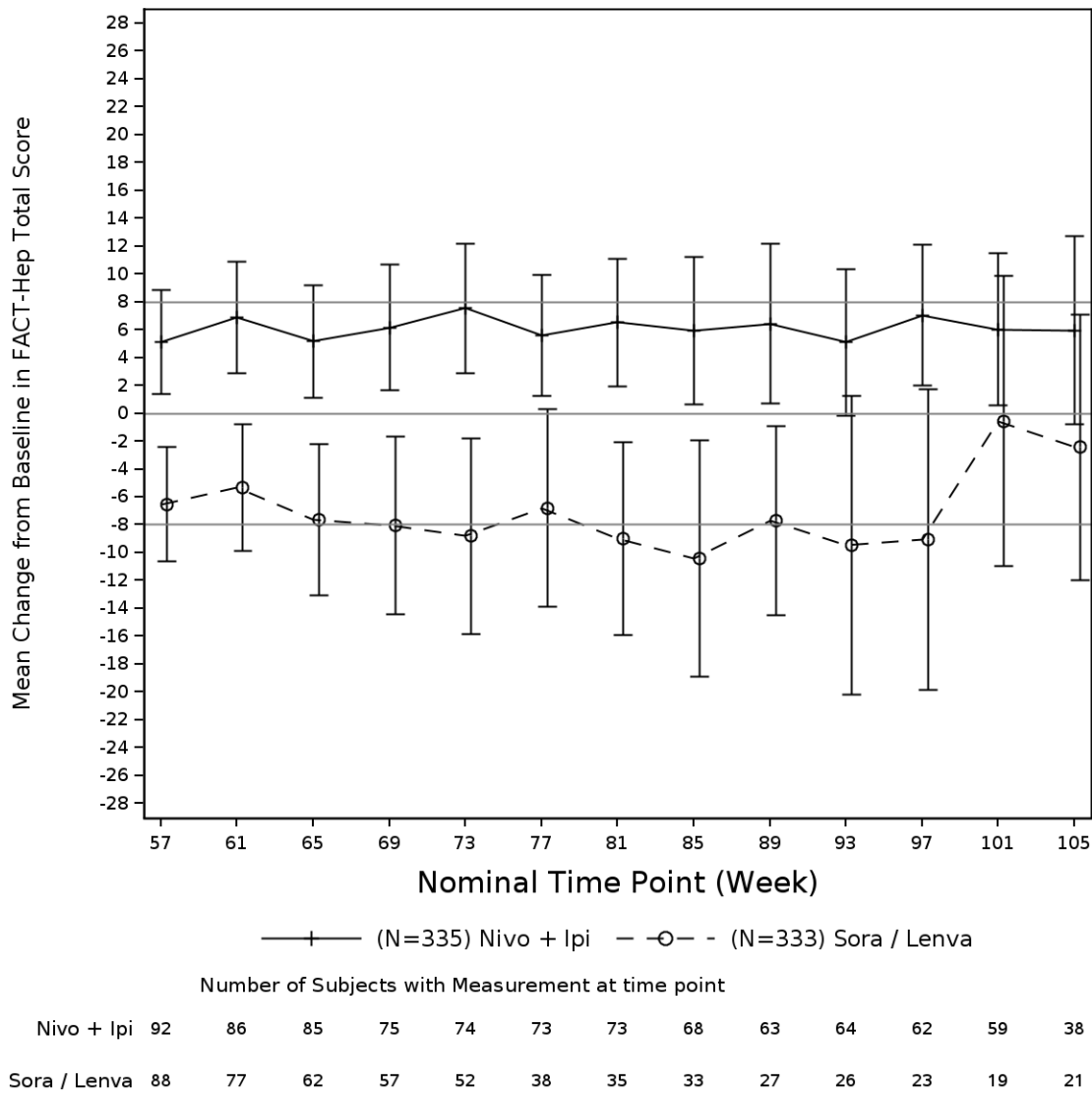
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Program Name:  rq-sy-chqbsl.sas                                20MAR2024:05:26:49

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Protocol: CA2099DW

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Figure 14.7.2.1.1:
Mean Changes in FACT-Hep Total Score from Baseline - All Randomized Subjects

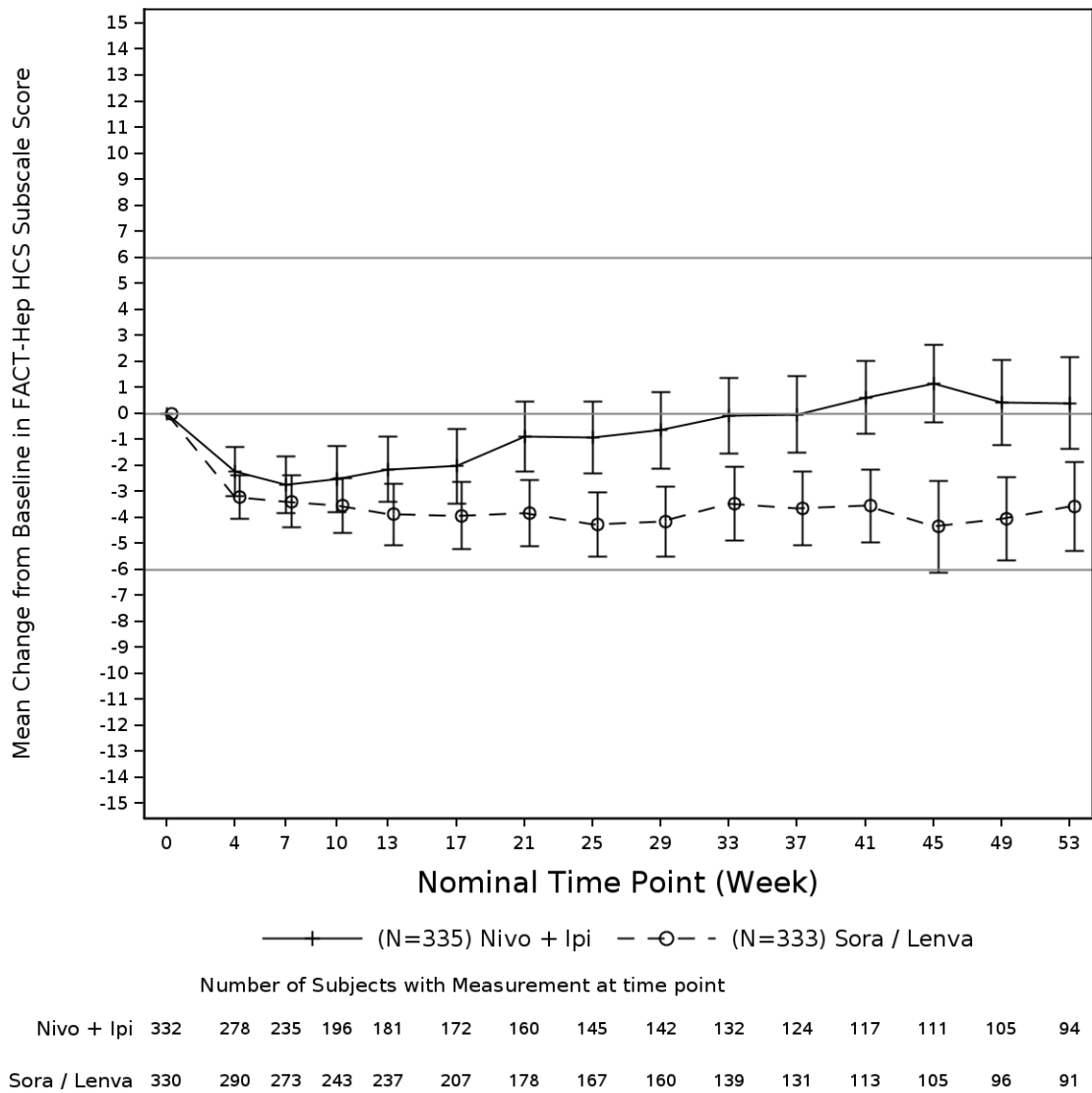


Error bars represent standard error for the mean.
Horizontal reference line indicates a minimally important difference (MID), considered a change ≥ 8 points from baseline.
Only time points where data available for ≥ 5 subjects in each treatment group are plotted.
Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/figures
Program Name: rg-sy-chgbsl.sas 20MAR2024:05:26:49

Protocol: CA2099DW

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Figure 14.7.2.1.2:
Mean Changes in HCS Score from Baseline - All Randomized Subjects

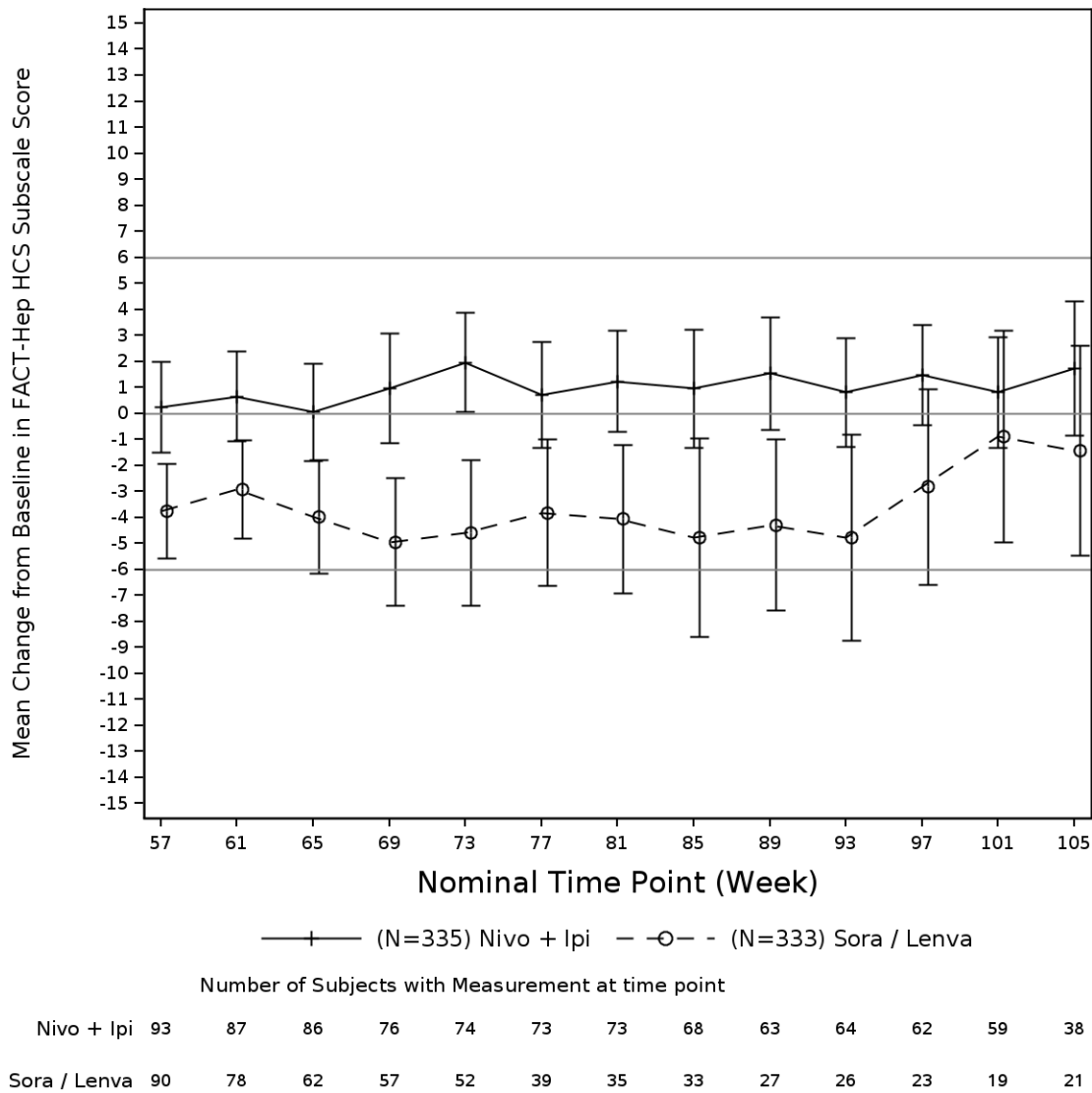


Error bars represent standard error for the mean.
Horizontal reference line indicates a minimally important difference (MID), considered a change ≥ 6 points from baseline.
HCS=Hepatobiliary Cancer Subscale
Only time points where data available for ≥ 5 subjects in each treatment group are plotted.
Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/figures
Program Name: rg-sy-chgbsl.sas 20MAR2024:05:26:53

Protocol: CA2099DW

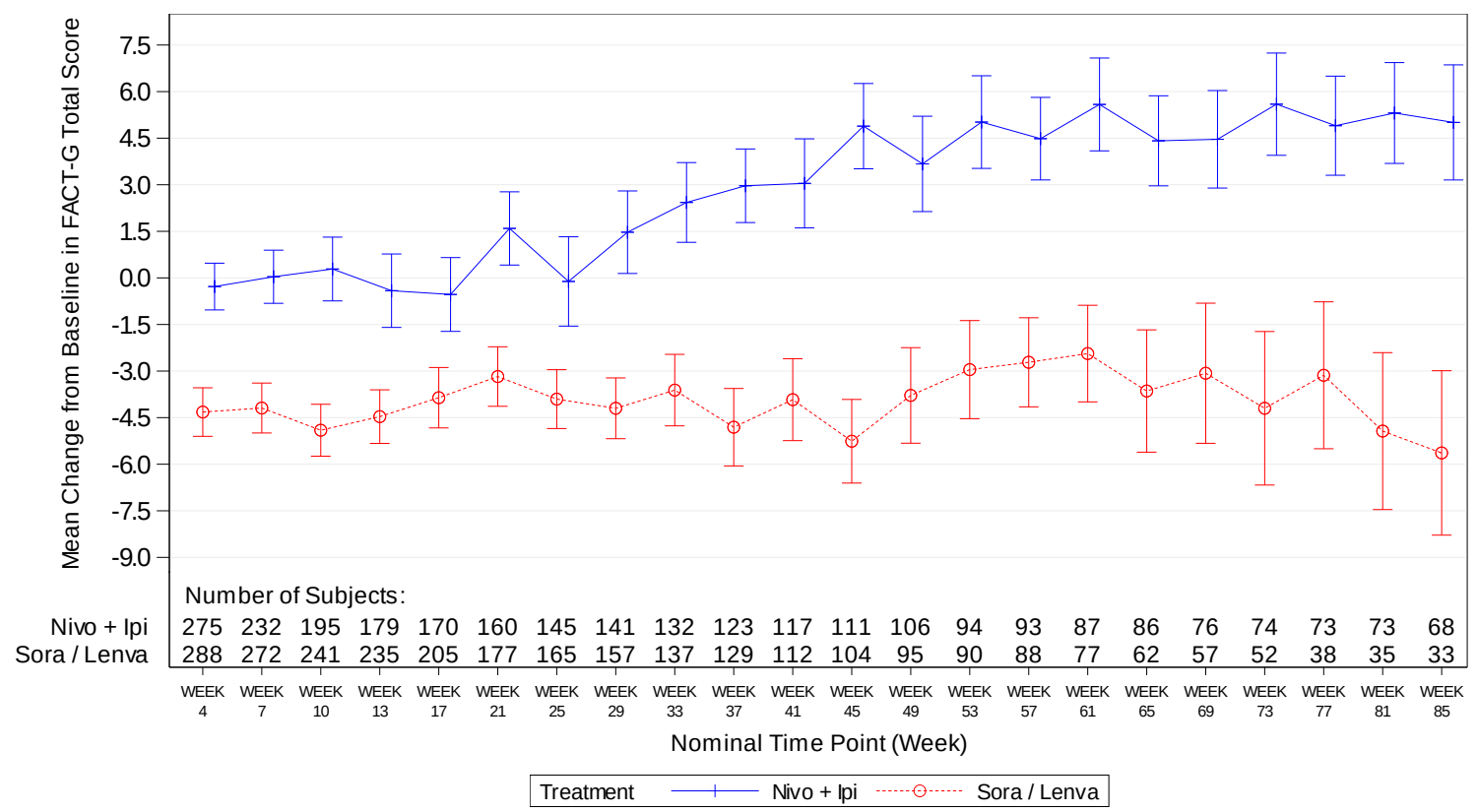
Page 2 of 2

Figure 14.7.2.1.2:
Mean Changes in HCS Score from Baseline - All Randomized Subjects



Error bars represent standard error for the mean.
Horizontal reference line indicates a minimally important difference (MID), considered a change ≥ 6 points from baseline.
HCS=Hepatobiliary Cancer Subscale
Only time points where data available for ≥ 5 subjects in each treatment group are plotted.
Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/figures
Program Name: rg-sy-chgbsl.sas 20MAR2024:05:26:53

Figure 4.5
Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - General (FACT-G) - Total Score - All Randomized Subjects



Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 16.2 points decrease from baseline) in the Total Score of the FACT-G
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

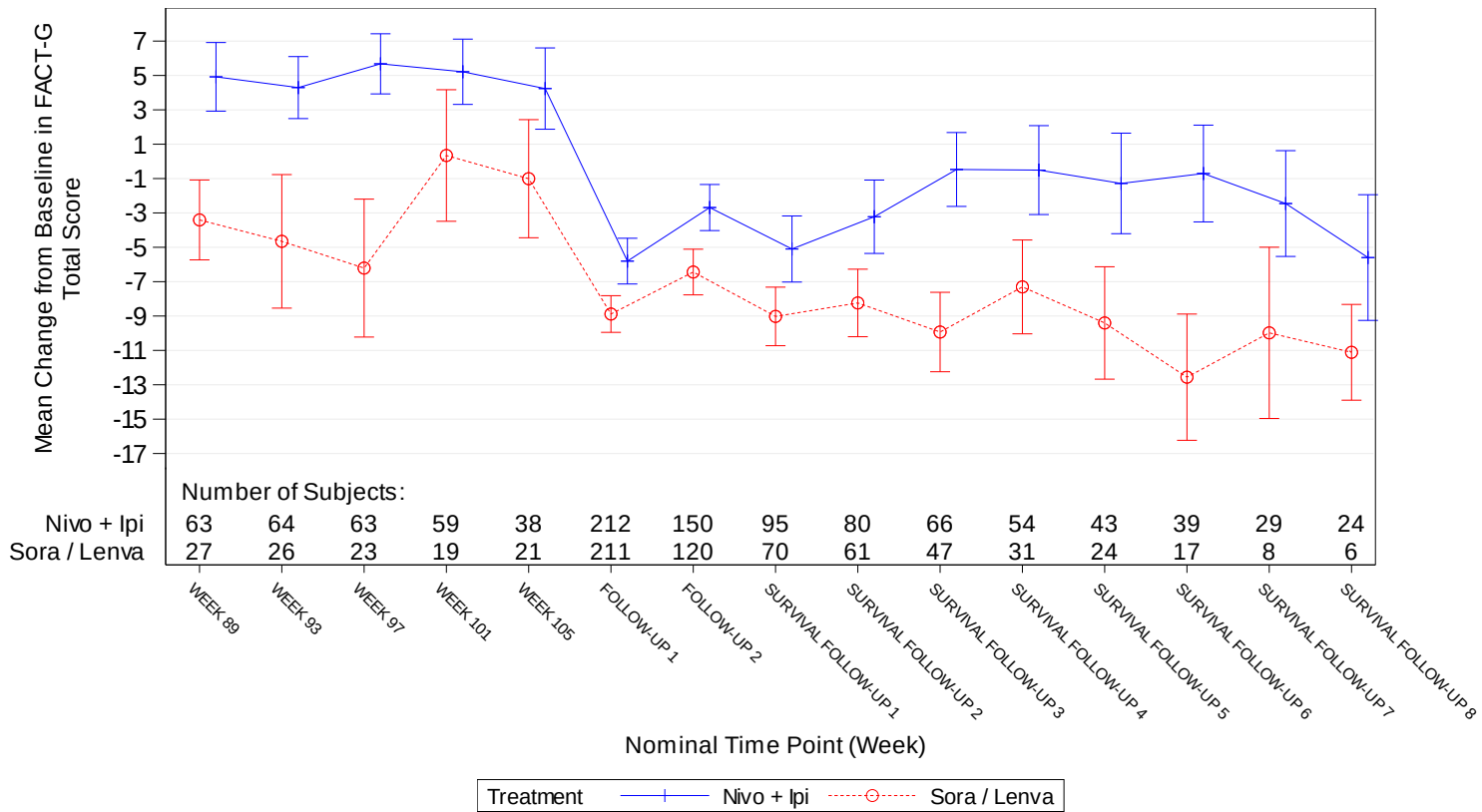
25FEB2025:12:10:42

Protocol: CA209-9DW

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Figure 4.5

Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - General (FACT-G) - Total Score - All Randomized Subjects

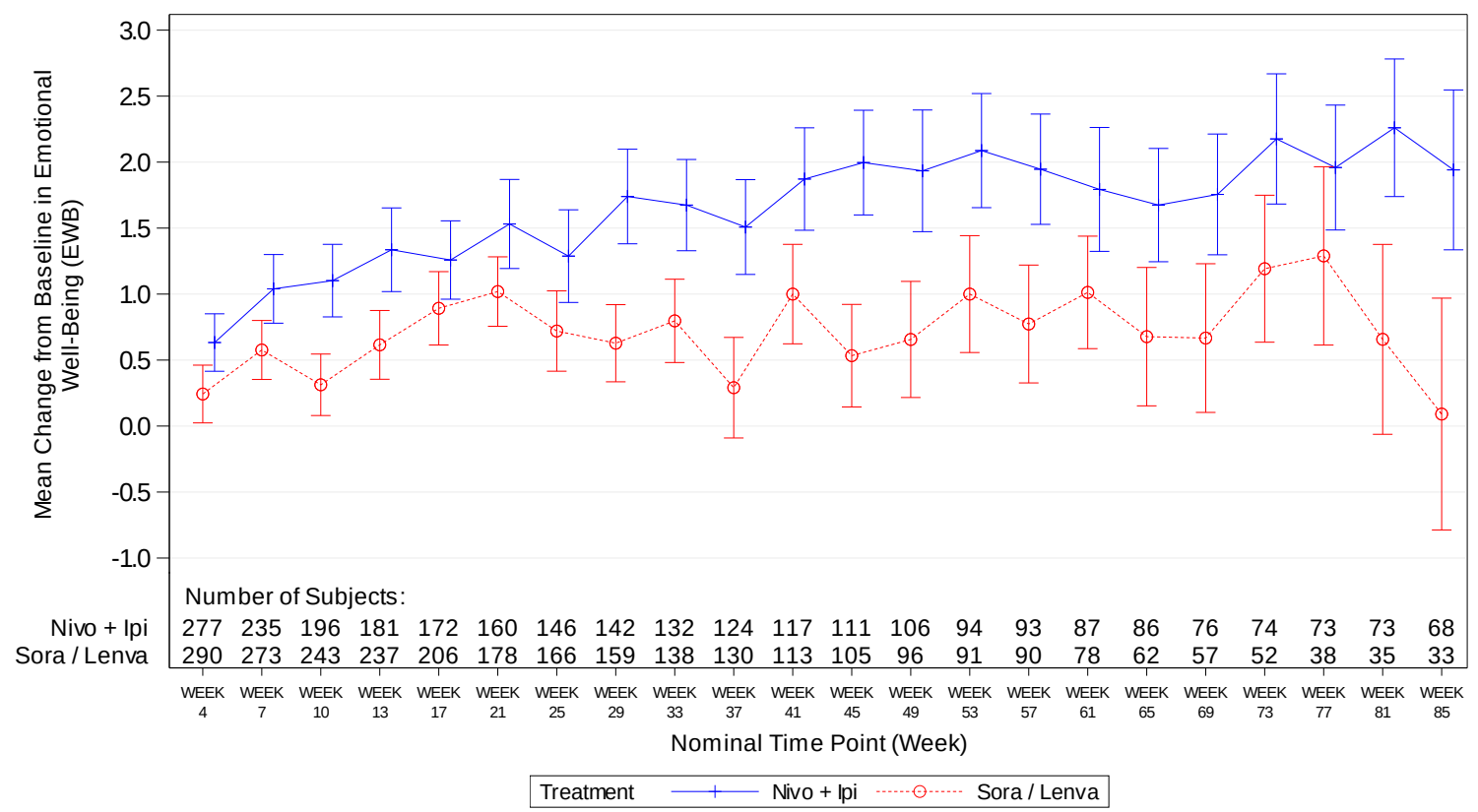


Error bars represent standard error for the mean.
Only time points where data available for ≥ 5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 16.2 points decrease from baseline) in the Total Score of the FACT-G
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

25FEB2025:12:10:42

Figure 4.3

Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Emotional Well-Being (EWB) - All Randomized Subjects

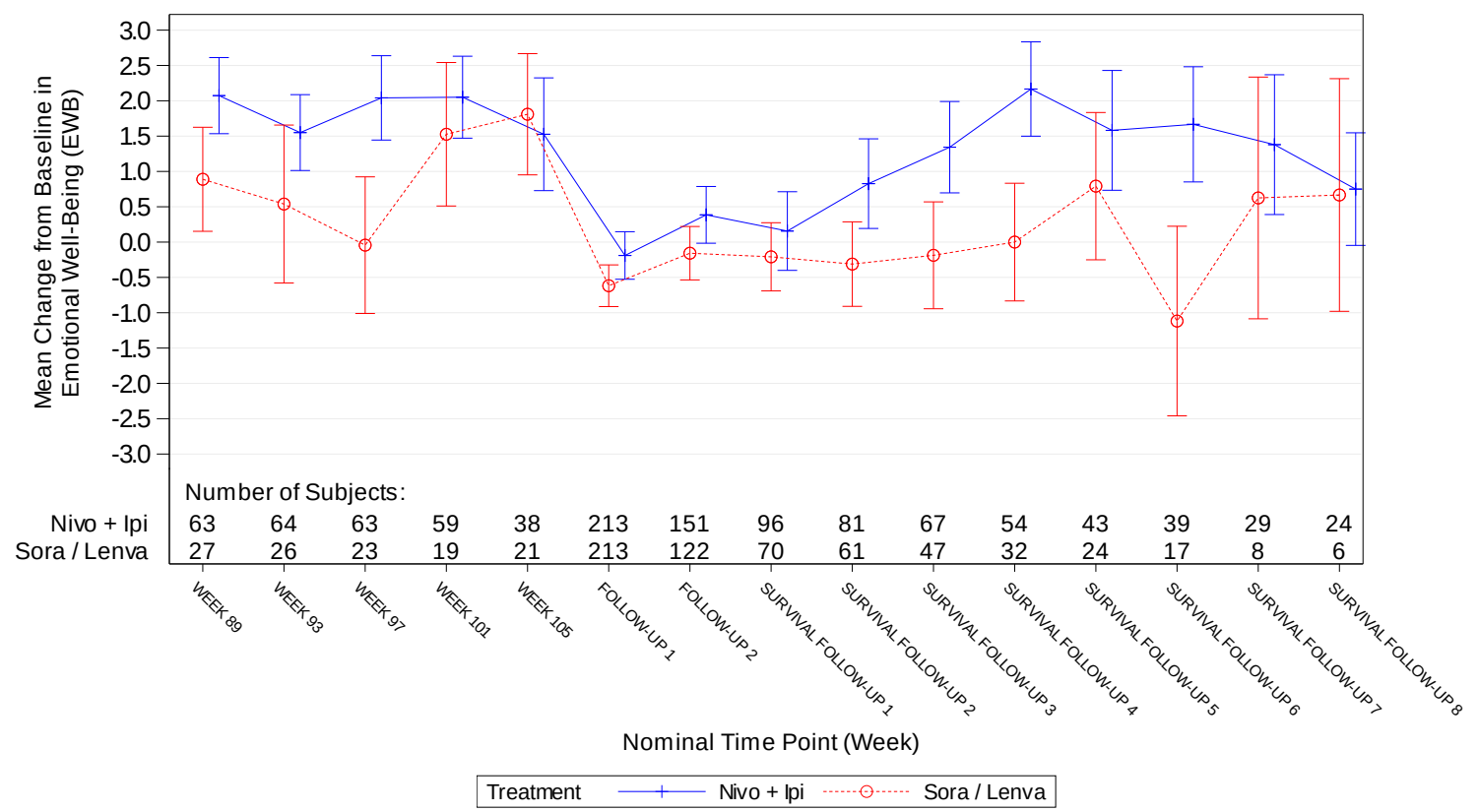


Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 3.6 points decrease from baseline) in the Emotional Well-Being (EWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

25FEB2025:12:10:39

Figure 4.3

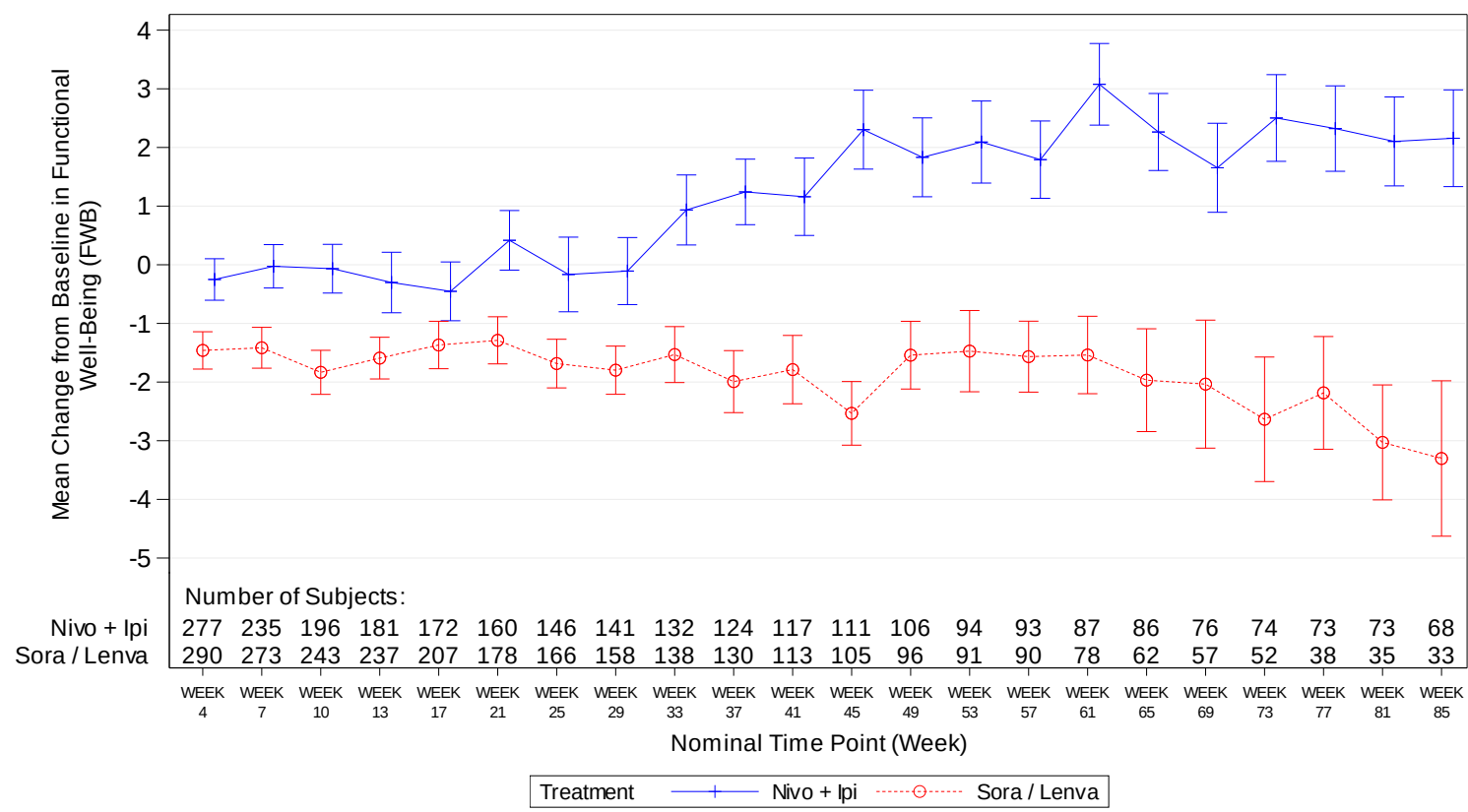
Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Emotional Well-Being (EWB) - All Randomized Subjects



Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 3.6 points decrease from baseline) in the Emotional Well-Being (EWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

25FEB2025:12:10:39

Figure 4.4
Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Functional Well-Being (FWB) - All Randomized Subjects

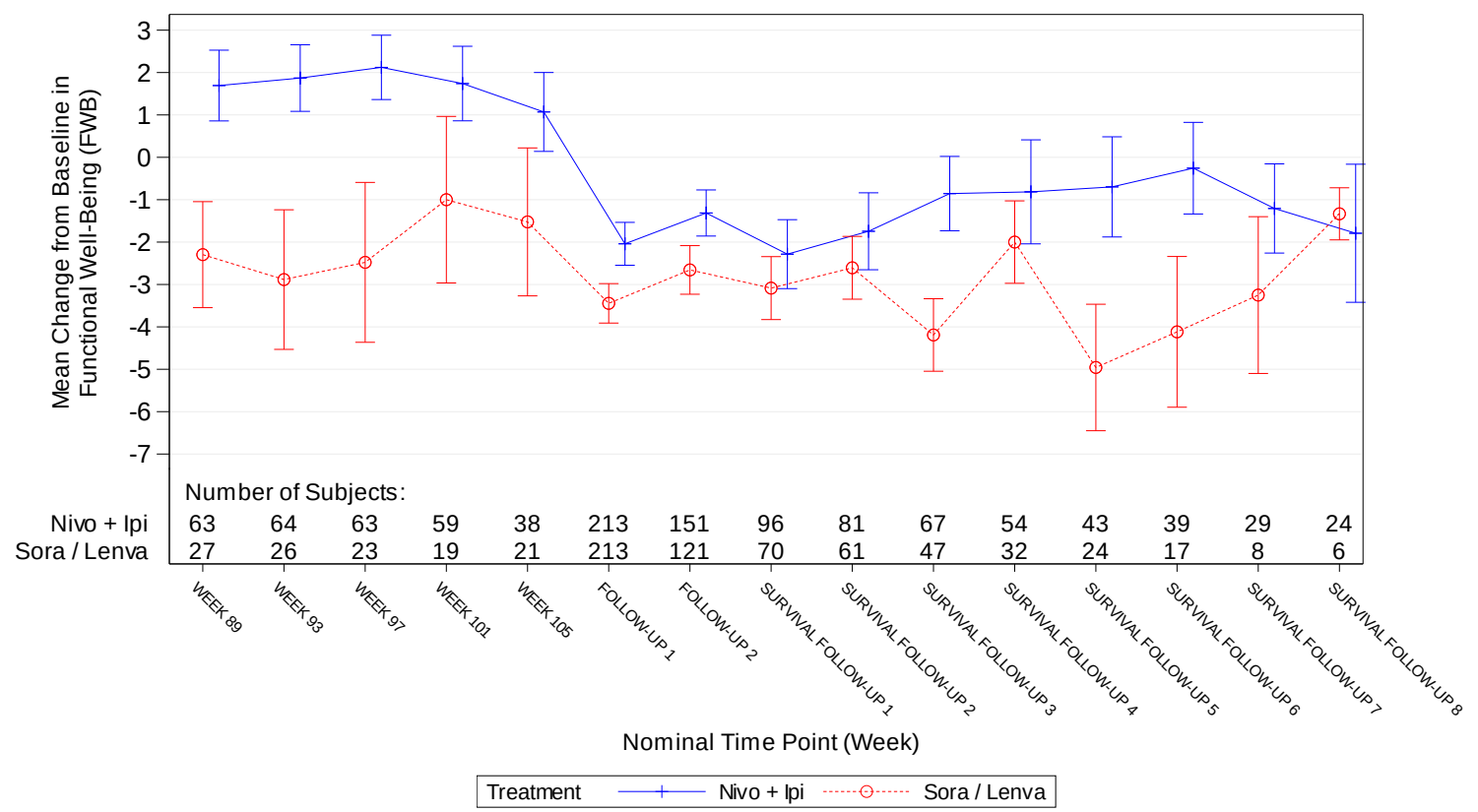


Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Functional Well-Being (FWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

25FEB2025:12:10:41

Figure 4.4

Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Functional Well-Being (FWB) - All Randomized Subjects

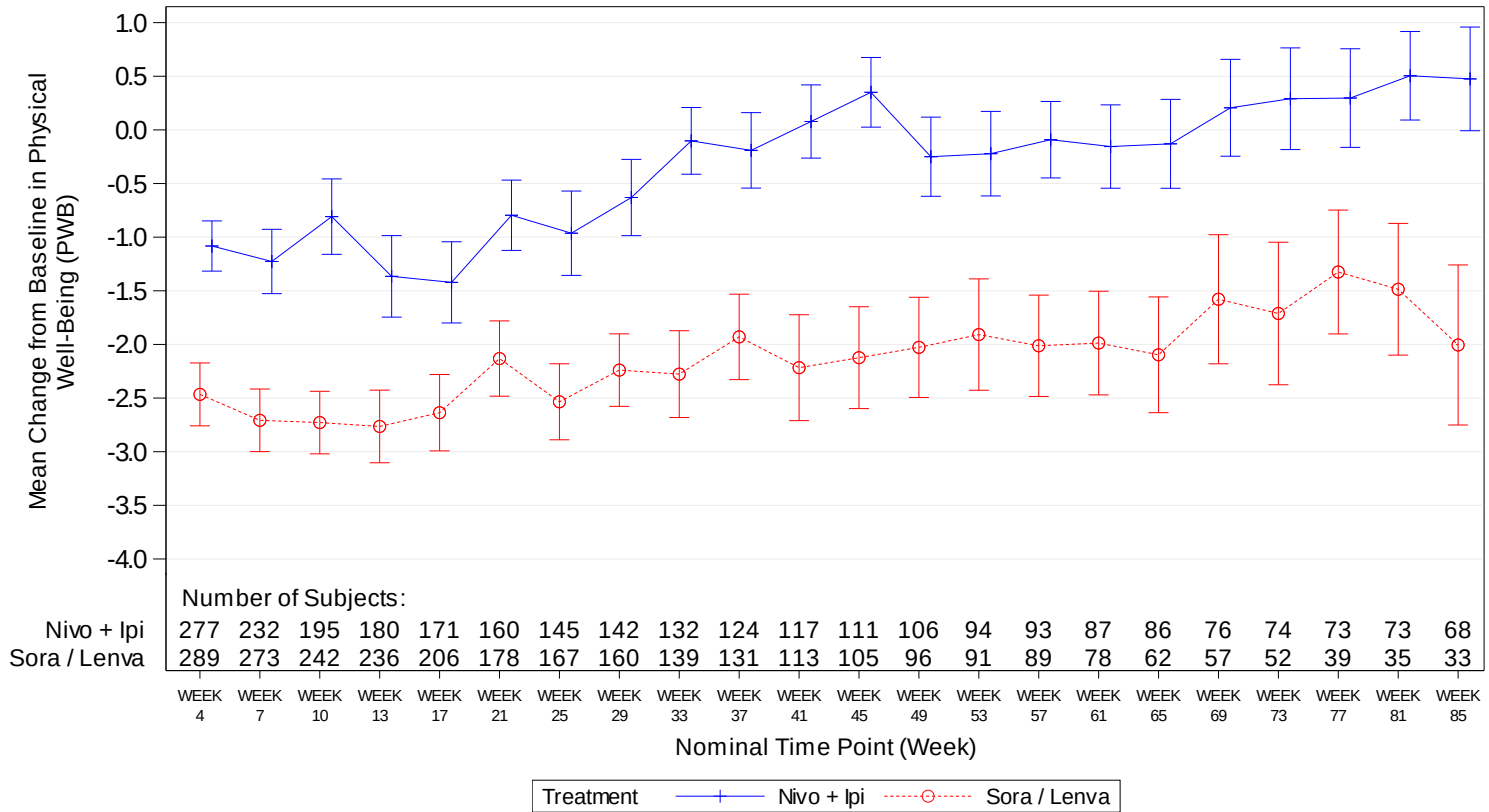


Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Functional Well-Being (FWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ibr2618.sas

25FEB2025:12:10:41

Figure 4.1

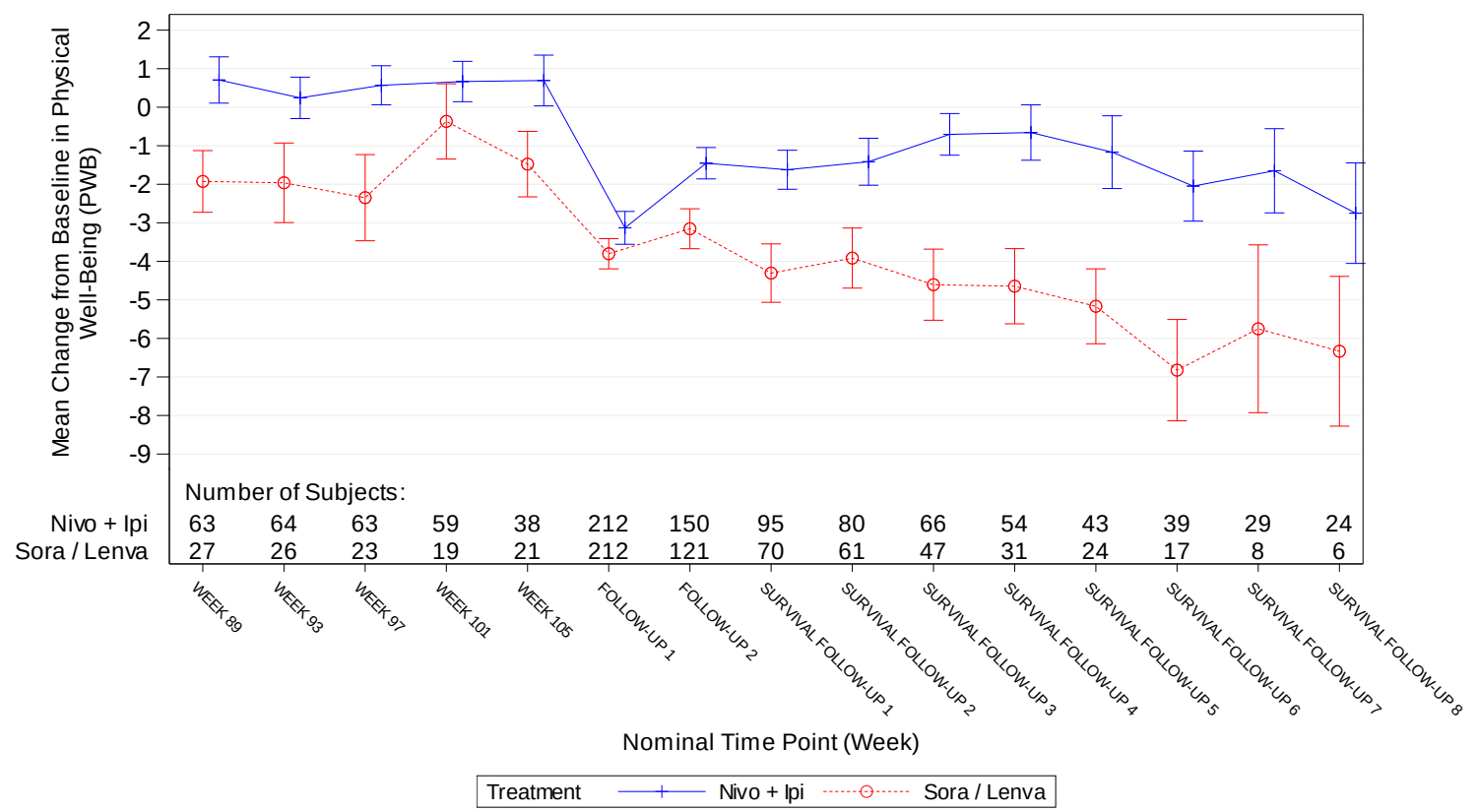
Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Physical Well-Being (PWB) - All Randomized Subjects



Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Physical Well-Being (PWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
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Program Name: rg-ef-lpf-ebr2618.sas

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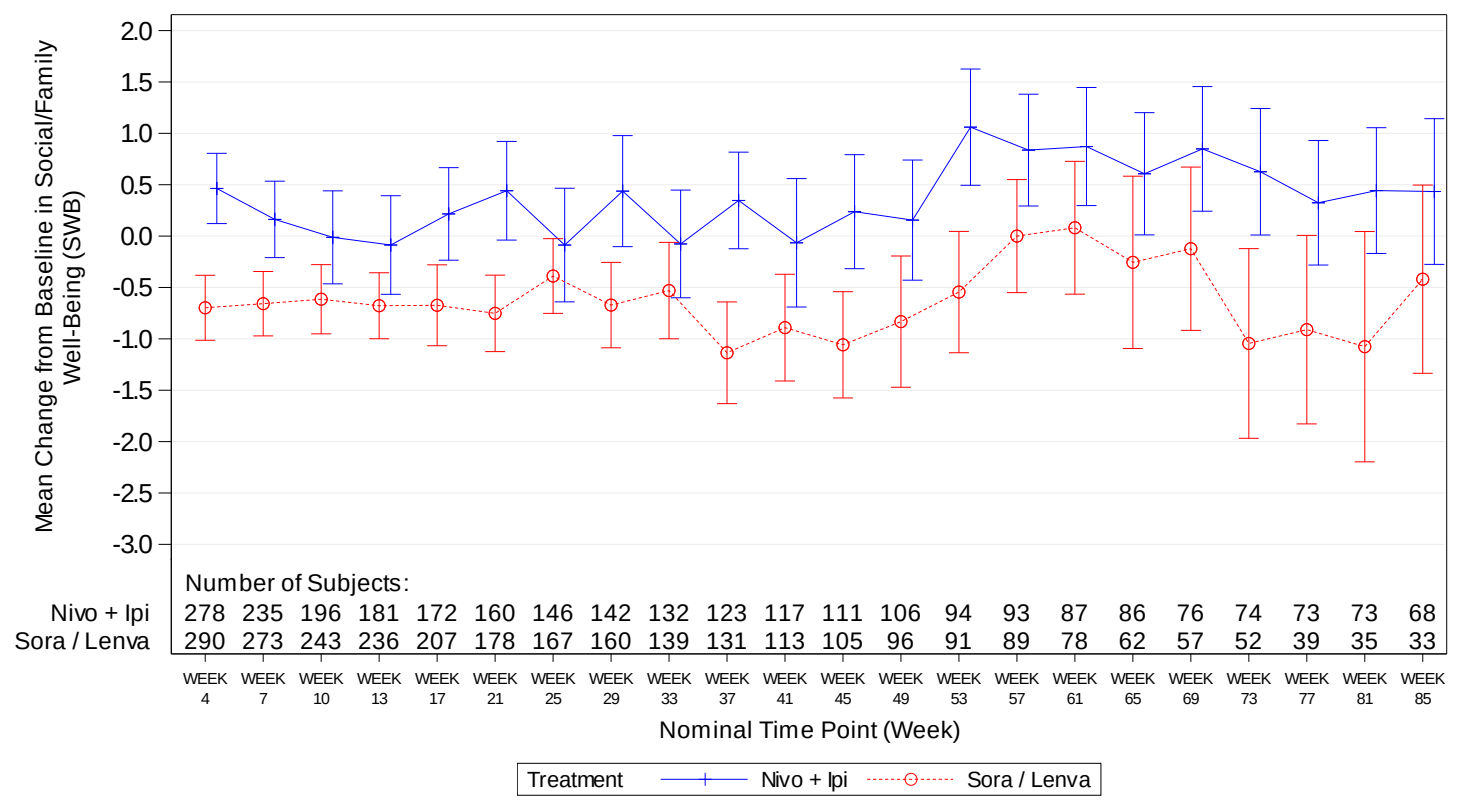
Figure 4.1
Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Physical Well-Being (PWB) - All Randomized Subjects



Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Physical Well-Being (PWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

25FEB2025:12:10:33

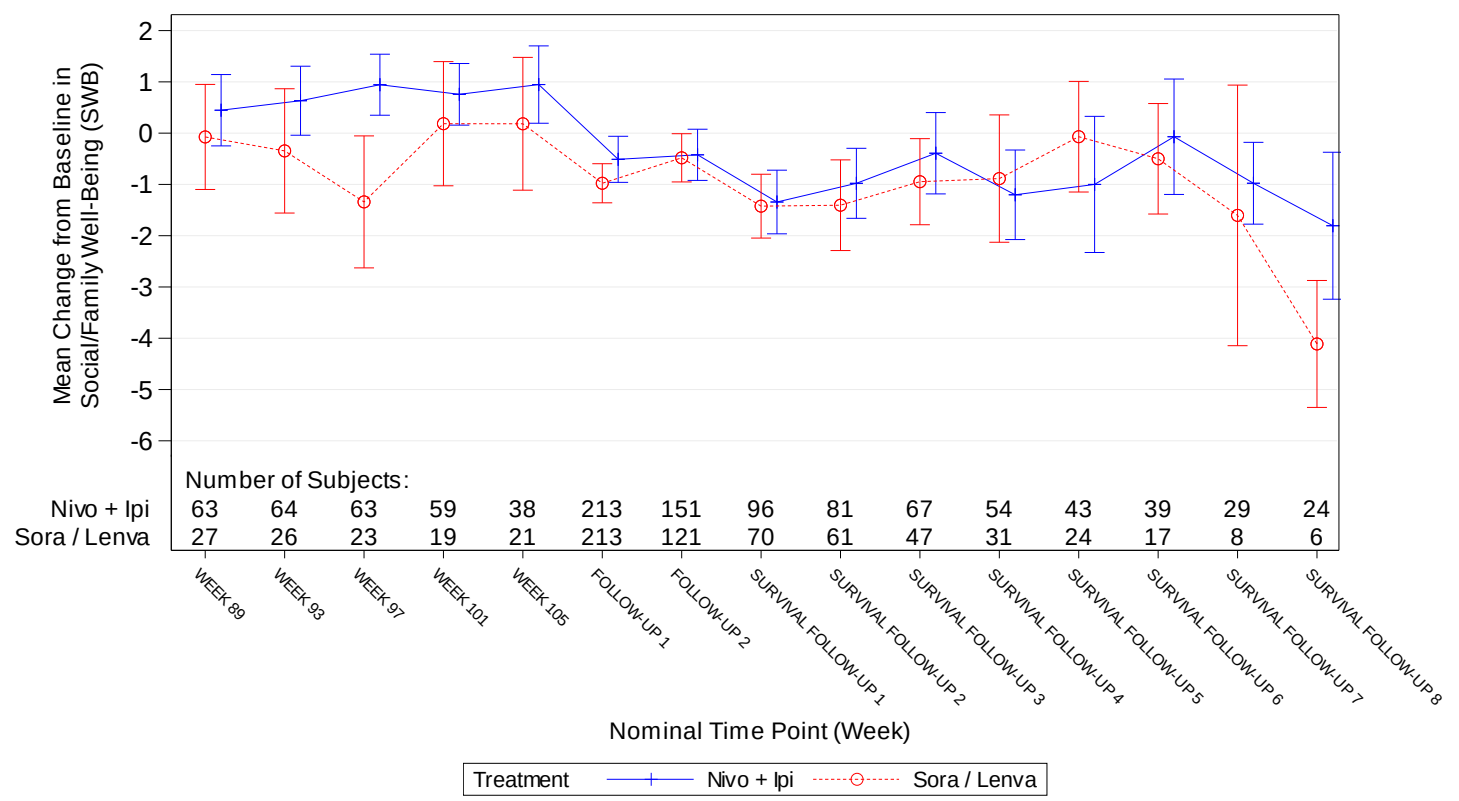
Figure 4.2
Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Social/Family Well-Being (SWB) - All Randomized Subjects



Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Social/Family Well-Being (SWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

25FEB2025:12:10:38

Figure 4.2
Line plot of Mean Change from Baseline - Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep) - Social/Family Well-Being (SWB) - All Randomized Subjects



Error bars represent standard error for the mean.
Only time points where data available for >=5 subjects in each treatment arm are plotted.
First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Social/Family Well-Being (SWB) questionnaire scale of the FACT-Hep
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/figures
Program Name: rg-ef-lpf-ebr2618.sas

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Protocol: CA209-9DW

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	332	331 (99.7)	0.48 (0.39, 0.56)	325	323 (99.4)	0.39 (0.30, 0.49)	0.97 (0.83, 1.14)	0.7959
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	332	216 (65.1)	1.48 (1.05, 2.10)	325	180 (55.4)	4.67 (2.96, 9.92)	1.55 (1.27, 1.89)	<0.0001*
PRURITUS	332	116 (34.9)	N.A. (19.78, N.A.)	325	23 (7.1)	N.A.	6.46 (4.12, 10.12)	<0.0001*
RASH	332	82 (24.7)	N.A.	325	33 (10.2)	N.A.	2.77 (1.84, 4.18)	<0.0001*
RASH MACULO-PAPULAR	332	19 (5.7)	N.A.	325	4 (1.2)	N.A.	4.79 (1.63, 14.07)	0.0017*
DRY SKIN	332	11 (3.3)	N.A.	325	10 (3.1)	N.A.	1.13 (0.48, 2.66)	0.7812
PALMAR-PLANTAR ERYTHRODYSAES- THESIA SYNDROME	332	10 (3.0)	N.A.	325	105 (32.3)	N.A.	0.08 (0.04, 0.15)	<0.0001*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Protocol: CA209-9DW

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
ALOPECIA	332	5 (1.5)	N.A.	325	19 (5.8)	N.A.	0.28 (0.11, 0.76)	0.0077*
GASTROINTESTINAL DISORDERS	332	200 (60.2)	3.94 (2.86, 6.08)	325	241 (74.2)	1.77 (1.35, 2.66)	0.66 (0.54, 0.79)	<0.0001*
DIARRHOEA	332	77 (23.2)	N.A.	325	133 (40.9)	14.65 (11.24, 20.76)	0.54 (0.40, 0.71)	<0.0001*
NAUSEA	332	34 (10.2)	N.A.	325	54 (16.6)	N.A.	0.62 (0.40, 0.96)	0.0291*
CONSTIPATION	332	33 (9.9)	N.A.	325	52 (16.0)	N.A.	0.60 (0.39, 0.94)	0.0228*
ASCITES	332	32 (9.6)	N.A.	325	31 (9.5)	N.A.	1.05 (0.64, 1.73)	0.8355
ABDOMINAL PAIN	332	27 (8.1)	N.A.	325	56 (17.2)	N.A. (34.76, N.A.)	0.46 (0.29, 0.73)	0.0008*
VOMITING	332	26 (7.8)	N.A.	325	36 (11.1)	N.A.	0.71 (0.43, 1.17)	0.1787

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
ABDOMINAL PAIN UPPER	332	21 (6.3)	N.A.	325	33 (10.2)	N.A.	0.62 (0.36, 1.08)	0.0865
COLITIS	332	16 (4.8)	N.A.	325	0	N.E.	N.E.	<0.0001*
DRY MOUTH	332	14 (4.2)	N.A.	325	12 (3.7)	N.A.	1.17 (0.54, 2.54)	0.6921
ABDOMINAL DISTENSION	332	13 (3.9)	N.A.	325	24 (7.4)	N.A.	0.55 (0.28, 1.08)	0.0791
DYSPEPSIA	332	10 (3.0)	N.A.	325	20 (6.2)	N.A.	0.53 (0.25, 1.13)	0.0956
STOMATITIS	332	7 (2.1)	N.A.	325	29 (8.9)	N.A.	0.24 (0.10, 0.54)	0.0002*
GASTROOESOPHAGEAL REFLUX DISEASE	332	6 (1.8)	N.A.	325	10 (3.1)	N.A.	0.59 (0.21, 1.64)	0.3110
HAEMORRHOIDS	332	2 (0.6)	N.A.	325	11 (3.4)	N.A.	0.19 (0.04, 0.84)	0.0140*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
INVESTIGATIONS	332	191 (57.5)	2.92 (2.10, 6.51)	325	174 (53.5)	7.82 (4.63, 10.12)	1.24 (1.01, 1.53)	0.0393*
ASPARTATE AMINOTRANSFERASE INCREASED	332	99 (29.8)	N.A.	325	47 (14.5)	N.A.	2.43 (1.72, 3.45)	<0.0001*
ALANINE AMINOTRANSFERASE INCREASED	332	82 (24.7)	N.A.	325	36 (11.1)	N.A.	2.62 (1.77, 3.89)	<0.0001*
LIPASE INCREASED	332	61 (18.4)	N.A.	325	25 (7.7)	N.A.	2.68 (1.68, 4.27)	<0.0001*
AMYLASE INCREASED	332	51 (15.4)	N.A.	325	13 (4.0)	N.A.	4.19 (2.28, 7.73)	<0.0001*
BLOOD BILIRUBIN INCREASED	332	44 (13.3)	N.A.	325	35 (10.8)	N.A.	1.31 (0.84, 2.05)	0.2290
WEIGHT DECREASED	332	31 (9.3)	N.A.	325	67 (20.6)	N.A.	0.43 (0.28, 0.67)	<0.0001*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
PLATELET COUNT DECREASED	332	27 (8.1)	N.A.	325	28 (8.6)	N.A.	0.95 (0.56, 1.62)	0.8606
BLOOD ALKALINE PHOSPHATASE INCREASED	332	15 (4.5)	N.A.	325	11 (3.4)	N.A.	1.38 (0.63, 3.01)	0.4172
BLOOD CREATININE INCREASED	332	15 (4.5)	N.A.	325	15 (4.6)	43.47 (N.A., N.A.)	1.04 (0.50, 2.17)	0.9108
BLOOD MAGNESIUM DECREASED	332	11 (3.3)	N.A.	325	0	N.E.	N.E.	0.0014*
BLOOD THYROID STIMULATING HORMONE INCREASED	332	8 (2.4)	N.A.	325	13 (4.0)	N.A.	0.61 (0.25, 1.47)	0.2656
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	332	181 (54.5)	5.65 (3.52, 8.28)	325	186 (57.2)	5.55 (3.42, 8.31)	0.92 (0.75, 1.13)	0.4164
ASTHENIA	332	66 (19.9)	N.A.	325	68 (20.9)	N.A.	0.95 (0.68, 1.33)	0.7609

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
PYREXIA	332	52 (15.7)	N.A.	325	32 (9.8)	N.A.	1.63 (1.04, 2.54)	0.0312*
FATIGUE	332	49 (14.8)	N.A.	325	64 (19.7)	N.A.	0.76 (0.52, 1.10)	0.1395
OEDEMA PERIPHERAL	332	42 (12.7)	N.A.	325	41 (12.6)	N.A.	1.05 (0.68, 1.62)	0.8235
MALAISE	332	9 (2.7)	N.A.	325	13 (4.0)	N.A.	0.70 (0.30, 1.64)	0.4079
MUCOSAL INFLAMMATION	332	7 (2.1)	N.A.	325	19 (5.8)	N.A.	0.37 (0.16, 0.88)	0.0198*
METABOLISM AND NUTRITION DISORDERS	332	155 (46.7)	11.17 (6.05, N.A.)	325	151 (46.5)	13.34 (7.33, 18.50)	1.00 (0.80, 1.25)	0.9914
DECREASED APPETITE	332	59 (17.8)	N.A.	325	92 (28.3)	N.A. (25.23, N.A.)	0.61 (0.44, 0.85)	0.0029*
HYPOALBUMINAEMIA	332	31 (9.3)	N.A.	325	35 (10.8)	N.A.	0.85 (0.53, 1.39)	0.5216

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
HYPONATRAEMIA	332	30 (9.0)	N.A.	325	14 (4.3)	N.A.	2.27 (1.20, 4.29)	0.0092*
HYPERGLYCAEMIA	332	29 (8.7)	N.A.	325	8 (2.5)	N.A.	4.01 (1.83, 8.78)	0.0002*
HYPOKALAEMIA	332	17 (5.1)	N.A.	325	10 (3.1)	N.A.	1.73 (0.79, 3.80)	0.1672
HYPERKALAEMIA	332	12 (3.6)	N.A.	325	15 (4.6)	N.A.	0.78 (0.36, 1.69)	0.5316
HYPOMAGNESAEMIA	332	11 (3.3)	N.A.	325	19 (5.8)	N.A.	0.65 (0.31, 1.39)	0.2673
HYPOPHOSPHATAEMIA	332	5 (1.5)	N.A.	325	12 (3.7)	N.A.	0.41 (0.14, 1.17)	0.0855
INFECTIONS AND INFESTATIONS	332	130 (39.2)	17.18 (12.91, 22.97)	325	101 (31.1)	25.79 (16.30, N.A.)	1.31 (1.01, 1.71)	0.0404*
COVID-19	332	32 (9.6)	N.A.	325	19 (5.8)	N.A.	1.64 (0.92, 2.93)	0.0870

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
PNEUMONIA	332	17 (5.1)	N.A.	325	7 (2.2)	N.A.	2.23 (0.91, 5.43)	0.0711
URINARY TRACT INFECTION	332	14 (4.2)	N.A.	325	21 (6.5)	N.A.	0.63 (0.31, 1.27)	0.1937
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	332	103 (31.0)	N.A. (21.19, N.A.)	325	113 (34.8)	N.A. (20.37, N.A.)	0.82 (0.63, 1.07)	0.1503
COUGH	332	44 (13.3)	N.A.	325	23 (7.1)	N.A.	1.93 (1.17, 3.21)	0.0094*
DYSPNOEA	332	28 (8.4)	N.A.	325	15 (4.6)	N.A.	1.91 (1.02, 3.58)	0.0401*
PNEUMONITIS	332	10 (3.0)	N.A.	325	1 (0.3)	N.A.	10.86 (1.39, 85.02)	0.0044*
EPISTAXIS	332	8 (2.4)	N.A.	325	20 (6.2)	N.A.	0.38 (0.17, 0.88)	0.0183*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
DYSPHONIA	332	7 (2.1)	N.A.	325	60 (18.5)	N.A.	0.10 (0.05, 0.23)	<0.0001*
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	332	102 (30.7)	N.A. (24.54, N.A.)	325	122 (37.5)	23.00 (14.69, N.A.)	0.79 (0.60, 1.02)	0.0739
ARTHRALGIA	332	44 (13.3)	N.A.	325	43 (13.2)	N.A.	1.02 (0.67, 1.55)	0.9322
BACK PAIN	332	24 (7.2)	N.A.	325	29 (8.9)	N.A.	0.84 (0.49, 1.45)	0.5344
MYALGIA	332	20 (6.0)	N.A.	325	24 (7.4)	N.A.	0.80 (0.44, 1.45)	0.4541
PAIN IN EXTREMITY	332	14 (4.2)	N.A.	325	13 (4.0)	N.A.	1.13 (0.53, 2.41)	0.7492
MUSCLE SPASMS	332	12 (3.6)	N.A.	325	10 (3.1)	N.A.	1.28 (0.55, 2.97)	0.5601
MUSCULOSKELETAL CHEST PAIN	332	1 (0.3)	N.A.	325	11 (3.4)	44.81 (N.A., N.A.)	0.09 (0.01, 0.74)	0.0053*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
ENDOCRINE DISORDERS	332	101 (30.4)	N.A.	325	105 (32.3)	N.A. (21.72, N.A.)	0.95 (0.72, 1.25)	0.7246
HYPOTHYROIDISM	332	49 (14.8)	N.A.	325	88 (27.1)	N.A.	0.50 (0.36, 0.72)	<0.0001*
HYPERTHYROIDISM	332	37 (11.1)	N.A.	325	5 (1.5)	N.A.	7.86 (3.09, 20.01)	<0.0001*
ADRENAL INSUFFICIENCY	332	18 (5.4)	N.A.	325	0	N.E.	N.E.	<0.0001*
THYROIDITIS	332	16 (4.8)	N.A.	325	14 (4.3)	N.A.	1.19 (0.58, 2.45)	0.6341
BLOOD AND LYMPHATIC SYSTEM DISORDERS	332	83 (25.0)	N.A.	325	71 (21.8)	N.A.	1.22 (0.89, 1.67)	0.2231
ANAEMIA	332	46 (13.9)	N.A.	325	29 (8.9)	N.A.	1.79 (1.12, 2.85)	0.0138*
THROMBOCYTOPENIA	332	22 (6.6)	N.A.	325	38 (11.7)	N.A.	0.54 (0.32, 0.92)	0.0204*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
NEUTROPENIA	332	21 (6.3)	N.A.	325	17 (5.2)	N.A. (34.27, N.A.)	1.34 (0.70, 2.58)	0.3738
EOSINOPHILIA	332	12 (3.6)	N.A.	325	2 (0.6)	N.A.	5.80 (1.29, 26.03)	0.0094*
LEUKOPENIA	332	10 (3.0)	N.A.	325	9 (2.8)	N.A.	1.15 (0.46, 2.83)	0.7681
NERVOUS SYSTEM DISORDERS	332	83 (25.0)	N.A.	325	92 (28.3)	N.A. (22.51, N.A.)	0.90 (0.67, 1.22)	0.5047
HEADACHE	332	29 (8.7)	N.A.	325	37 (11.4)	N.A.	0.78 (0.48, 1.27)	0.3093
DIZZINESS	332	12 (3.6)	N.A.	325	15 (4.6)	42.81 (N.A., N.A.)	0.86 (0.40, 1.87)	0.7079
HEPATIC ENCEPHALOPATHY	332	10 (3.0)	N.A.	325	13 (4.0)	N.A.	0.76 (0.33, 1.75)	0.5146
HEPATOBIILIARY DISORDERS	332	70 (21.1)	N.A.	325	44 (13.5)	N.A. (36.93, N.A.)	1.73 (1.18, 2.54)	0.0045*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
HYPERBILIRUBI- NAEMIA	332	13 (3.9)	N.A.	325	11 (3.4)	N.A.	1.19 (0.53, 2.67)	0.6710
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	332	63 (19.0)	N.A.	325	86 (26.5)	N.A. (26.97, N.A.)	0.77 (0.55, 1.07)	0.1161
MALIGNANT NEOPLASM PROGRESSION	332	52 (15.7)	N.A.	325	74 (22.8)	N.A.	0.73 (0.51, 1.04)	0.0817
VASCULAR DISORDERS	332	56 (16.9)	N.A.	325	154 (47.4)	16.59 (3.71, N.A.)	0.27 (0.20, 0.36)	<0.0001*
HYPERTENSION	332	37 (11.1)	N.A.	325	145 (44.6)	21.26 (8.28, N.A.)	0.19 (0.13, 0.27)	<0.0001*
HYPOTENSION	332	11 (3.3)	N.A.	325	5 (1.5)	N.A.	2.18 (0.76, 6.29)	0.1389
RENAL AND URINARY DISORDERS	332	38 (11.4)	N.A.	325	96 (29.5)	30.16 (16.53, N.A.)	0.36 (0.24, 0.52)	<0.0001*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
ACUTE KIDNEY INJURY	332	13 (3.9)	N.A.	325	6 (1.8)	N.A.	2.23 (0.84, 5.88)	0.0966
PROTEINURIA	332	4 (1.2)	N.A.	325	71 (21.8)	N.A.	0.05 (0.02, 0.14)	<0.0001*
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	332	37 (11.1)	N.A.	325	19 (5.8)	44.81 (N.A., N.A.)	2.15 (1.22, 3.79)	0.0067*
PSYCHIATRIC DISORDERS	332	33 (9.9)	N.A.	325	34 (10.5)	N.A.	1.01 (0.62, 1.63)	0.9739
INSOMNIA	332	25 (7.5)	N.A.	325	21 (6.5)	N.A.	1.26 (0.70, 2.25)	0.4380
EYE DISORDERS	332	27 (8.1)	N.A.	325	17 (5.2)	N.A.	1.63 (0.88, 3.00)	0.1143
CARDIAC DISORDERS	332	21 (6.3)	N.A.	325	29 (8.9)	41.66 (N.A., N.A.)	0.77 (0.44, 1.37)	0.3756

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.1
Time to Event Analyses for Any TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
EAR AND LABYRINTH DISORDERS	332	10 (3.0)	N.A.	325	18 (5.5)	N.A.	0.52 (0.24, 1.14)	0.0980

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.
(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),
Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein
(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	332	254 (76.5)	2.43 (2.07, 2.92)	325	241 (74.2)	3.98 (3.32, 5.65)	1.13 (0.94, 1.35)	0.2004
INVESTIGATIONS	332	77 (23.2)	N.A.	325	53 (16.3)	N.A.	1.61 (1.13, 2.28)	0.0079*
ASPARTATE AMINOTRANSFERASE INCREASED	332	28 (8.4)	N.A.	325	7 (2.2)	N.A.	4.24 (1.85, 9.71)	0.0002*
LIPASE INCREASED	332	24 (7.2)	N.A.	325	5 (1.5)	N.A.	5.42 (2.06, 14.24)	0.0001*
ALANINE AMINOTRANSFERASE INCREASED	332	23 (6.9)	N.A.	325	6 (1.8)	N.A.	3.91 (1.59, 9.61)	0.0014*
GASTROINTESTINAL DISORDERS	332	54 (16.3)	N.A.	325	45 (13.8)	N.A.	1.23 (0.83, 1.83)	0.3058
ASCITES	332	11 (3.3)	N.A.	325	6 (1.8)	N.A.	2.01 (0.74, 5.44)	0.1621

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
DIARRHOEA	332	7 (2.1)	N.A.	325	12 (3.7)	N.A.	0.63 (0.25, 1.60)	0.3290
HEPATOBIILIARY DISORDERS	332	50 (15.1)	N.A.	325	27 (8.3)	N.A. (36.93, N.A.)	1.96 (1.22, 3.15)	0.0047*
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	332	50 (15.1)	N.A.	325	76 (23.4)	N.A.	0.69 (0.48, 0.99)	0.0410*
MALIGNANT NEOPLASM PROGRESSION	332	44 (13.3)	N.A.	325	68 (20.9)	N.A.	0.67 (0.45, 0.98)	0.0369*
INFECTIONS AND INFESTATIONS	332	46 (13.9)	N.A.	325	33 (10.2)	N.A.	1.41 (0.90, 2.23)	0.1346
METABOLISM AND NUTRITION DISORDERS	332	41 (12.3)	N.A.	325	30 (9.2)	N.A.	1.50 (0.93, 2.40)	0.0938
HYPONATRAEMIA	332	12 (3.6)	N.A.	325	8 (2.5)	N.A.	1.57 (0.64, 3.85)	0.3194

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 11.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
HYPERGLYCAEMIA	332	11 (3.3)	N.A.	325	1 (0.3)	N.A.	12.20 (1.57, 94.66)	0.0022*
BLOOD AND LYMPHATIC SYSTEM DISORDERS	332	25 (7.5)	N.A.	325	21 (6.5)	N.A.	1.21 (0.68, 2.18)	0.5160
ANAEMIA	332	12 (3.6)	N.A.	325	11 (3.4)	N.A.	1.18 (0.52, 2.72)	0.6914
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	332	25 (7.5)	N.A.	325	31 (9.5)	N.A.	0.84 (0.49, 1.42)	0.5107
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	332	22 (6.6)	N.A.	325	23 (7.1)	N.A.	0.92 (0.51, 1.65)	0.7741
PALMAR-PLANTAR ERYTHRODYSAES- THESIA SYNDROME	332	0	N.E.	325	13 (4.0)	N.A.	N.E.	0.0003*
NERVOUS SYSTEM DISORDERS	332	19 (5.7)	N.A.	325	17 (5.2)	N.A.	1.14 (0.59, 2.20)	0.6887

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 11.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
VASCULAR DISORDERS	332	18 (5.4)	N.A.	325	52 (16.0)	N.A.	0.32 (0.19, 0.55)	<0.0001*
HYPERTENSION	332	12 (3.6)	N.A.	325	43 (13.2)	N.A.	0.26 (0.14, 0.50)	<0.0001*
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	332	15 (4.5)	N.A.	325	8 (2.5)	N.A.	1.84 (0.78, 4.34)	0.1603
ENDOCRINE DISORDERS	332	13 (3.9)	N.A.	325	0	N.E.	N.E.	0.0002*
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	332	12 (3.6)	N.A.	325	6 (1.8)	N.A.	2.09 (0.78, 5.59)	0.1334
RENAL AND URINARY DISORDERS	332	11 (3.3)	N.A.	325	28 (8.6)	N.A.	0.41 (0.20, 0.82)	0.0094*
PROTEINURIA	332	0	N.E.	325	17 (5.2)	N.A.	N.E.	<0.0001*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.3
Time to Event Analyses for Serious TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
TOTAL SUBJECTS WITH AN EVENT	332	212 (63.9)	5.16 (3.84, 8.08)	325	175 (53.8)	11.33 (8.74, 14.85)	1.38 (1.13, 1.69)	0.0017*
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	332	51 (15.4)	N.A.	325	75 (23.1)	N.A.	0.71 (0.50, 1.02)	0.0656
MALIGNANT NEOPLASM PROGRESSION	332	44 (13.3)	N.A.	325	67 (20.6)	N.A.	0.68 (0.46, 1.00)	0.0463*
GASTROINTESTINAL DISORDERS	332	50 (15.1)	N.A.	325	40 (12.3)	N.A.	1.26 (0.83, 1.92)	0.2702
INFECTIONS AND INFESTATIONS	332	48 (14.5)	N.A.	325	33 (10.2)	N.A.	1.45 (0.92, 2.27)	0.1059
HEPATOBIILIARY DISORDERS	332	41 (12.3)	N.A.	325	21 (6.5)	N.A. (36.93, N.A.)	2.11 (1.24, 3.61)	0.0052*
NERVOUS SYSTEM DISORDERS	332	18 (5.4)	N.A.	325	20 (6.2)	N.A.	0.96 (0.50, 1.83)	0.8953

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 11.3
Time to Event Analyses for Serious TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	332	17 (5.1)	N.A.	325	25 (7.7)	N.A.	0.73 (0.39, 1.35)	0.3054
PYREXIA	332	6 (1.8)	N.A.	325	12 (3.7)	N.A.	0.50 (0.19, 1.33)	0.1531
ENDOCRINE DISORDERS	332	14 (4.2)	N.A.	325	0	N.E.	N.E.	<0.0001*
INVESTIGATIONS	332	13 (3.9)	N.A.	325	9 (2.8)	N.A.	1.43 (0.61, 3.36)	0.4030
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	332	13 (3.9)	N.A.	325	7 (2.2)	N.A.	1.79 (0.71, 4.50)	0.2104
METABOLISM AND NUTRITION DISORDERS	332	12 (3.6)	N.A.	325	11 (3.4)	N.A.	1.22 (0.54, 2.77)	0.6375
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	332	11 (3.3)	N.A.	325	6 (1.8)	N.A.	1.95 (0.72, 5.32)	0.1823

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Table 11.3
Time to Event Analyses for Serious TEAE
By SOC/PT
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
RENAL AND URINARY DISORDERS	332	11 (3.3)	N.A.	325	12 (3.7)	N.A.	0.93 (0.41, 2.11)	0.8536
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	332	11 (3.3)	N.A.	325	4 (1.2)	N.A.	2.60 (0.82, 8.23)	0.0914
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	332	10 (3.0)	N.A.	325	5 (1.5)	N.A.	2.00 (0.68, 5.87)	0.1986
VASCULAR DISORDERS	332	5 (1.5)	N.A.	325	10 (3.1)	N.A.	0.54 (0.18, 1.58)	0.2527

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-ebr2618.sas

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Protocol: CA2099DW

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Table 14.3.2.3.1.1
Adverse Events Leading to Discontinuation Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N = 332			Sora / Lenva N = 325		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	88 (26.5)	69 (20.8)	0	75 (23.1)	51 (15.7)	1 (0.3)
Hepatobiliary disorders	18 (5.4)	17 (5.1)	0	8 (2.5)	7 (2.2)	0
Autoimmune hepatitis	3 (0.9)	3 (0.9)	0	0	0	0
Immune-mediated hepatitis	3 (0.9)	3 (0.9)	0	0	0	0
Acute hepatic failure	2 (0.6)	2 (0.6)	0	0	0	0
Drug-induced liver injury	2 (0.6)	2 (0.6)	0	1 (0.3)	1 (0.3)	0
Hepatic failure	2 (0.6)	2 (0.6)	0	2 (0.6)	2 (0.6)	0
Hepatic cirrhosis	1 (0.3)	1 (0.3)	0	0	0	0
Hepatorenal syndrome	1 (0.3)	1 (0.3)	0	1 (0.3)	1 (0.3)	0
Hepatotoxicity	1 (0.3)	1 (0.3)	0	0	0	0
Hyperbilirubinaemia	1 (0.3)	0	0	0	0	0
Hypertransaminasaemia	1 (0.3)	1 (0.3)	0	0	0	0
Liver injury	1 (0.3)	1 (0.3)	0	0	0	0
Acute on chronic liver failure	0	0	0	1 (0.3)	1 (0.3)	0
Cholangitis	0	0	0	1 (0.3)	1 (0.3)	0
Cholestasis	0	0	0	2 (0.6)	1 (0.3)	0
Gastrointestinal disorders	11 (3.3)	10 (3.0)	0	5 (1.5)	2 (0.6)	0
Colitis	3 (0.9)	2 (0.6)	0	0	0	0
Immune-mediated enterocolitis	2 (0.6)	2 (0.6)	0	0	0	0
Pancreatitis	2 (0.6)	2 (0.6)	0	0	0	0
Abdominal pain	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0
Ascites	1 (0.3)	1 (0.3)	0	0	0	0
Diarrhoea	1 (0.3)	0	0	2 (0.6)	1 (0.3)	0
Enteritis	1 (0.3)	1 (0.3)	0	0	0	0
Enterocolitis haemorrhagic	1 (0.3)	1 (0.3)	0	0	0	0
Gastritis	1 (0.3)	1 (0.3)	0	0	0	0

MedDRA Version: 26.1

CTCAE Version 5.0

Includes events reported between first dose and 30 days after last dose of study therapy.

Program Source: /projects/bms247812/stats/interim/prog/tables/rt-ae-cat.sas

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Table 14.3.2.3.1.1
Adverse Events Leading to Discontinuation Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N = 332			Sora / Ienva N = 325		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Haematemesis	0	0	0	1 (0.3)	1 (0.3)	0
Melaena	0	0	0	1 (0.3)	1 (0.3)	0
Nausea	0	0	0	2 (0.6)	0	0
Vomiting	0	0	0	1 (0.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (2.7)	9 (2.7)	0	22 (6.8)	16 (4.9)	1 (0.3)
Malignant neoplasm progression	9 (2.7)	9 (2.7)	0	20 (6.2)	14 (4.3)	1 (0.3)
Follicular lymphoma	0	0	0	1 (0.3)	1 (0.3)	0
Metastases to central nervous system	0	0	0	1 (0.3)	1 (0.3)	0
Infections and infestations	8 (2.4)	7 (2.1)	0	5 (1.5)	5 (1.5)	0
COVID-19	2 (0.6)	2 (0.6)	0	0	0	0
COVID-19 pneumonia	2 (0.6)	2 (0.6)	0	0	0	0
Bronchiolitis	1 (0.3)	0	0	0	0	0
Meningitis aseptic	1 (0.3)	1 (0.3)	0	0	0	0
Pneumonia pneumococcal	1 (0.3)	1 (0.3)	0	0	0	0
Septic shock	1 (0.3)	1 (0.3)	0	2 (0.6)	2 (0.6)	0
Pneumonia	0	0	0	1 (0.3)	1 (0.3)	0
Pneumonia aspiration	0	0	0	1 (0.3)	1 (0.3)	0
Tuberculosis	0	0	0	1 (0.3)	1 (0.3)	0
Investigations	7 (2.1)	3 (0.9)	0	8 (2.5)	7 (2.2)	0
Aspartate aminotransferase increased	5 (1.5)	2 (0.6)	0	1 (0.3)	0	0
Alanine aminotransferase increased	3 (0.9)	1 (0.3)	0	0	0	0
Blood bilirubin increased	1 (0.3)	0	0	2 (0.6)	2 (0.6)	0
Lipase increased	1 (0.3)	1 (0.3)	0	0	0	0
Transaminases increased	1 (0.3)	0	0	0	0	0

MedDRA Version: 26.1

CTCAE Version 5.0

Includes events reported between first dose and 30 days after last dose of study therapy.

Program Source: /projects/bms247812/stats/interim/prog/tables/rt-ae-cat.sas

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Table 14.3.2.3.1.1
Adverse Events Leading to Discontinuation Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N = 332			Sora / Lenva N = 325		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Electrocardiogram QT prolonged	0	0	0	1 (0.3)	1 (0.3)	0
General physical condition abnormal	0	0	0	1 (0.3)	1 (0.3)	0
Platelet count decreased	0	0	0	1 (0.3)	1 (0.3)	0
Weight decreased	0	0	0	2 (0.6)	2 (0.6)	0
Musculoskeletal and connective tissue disorders	7 (2.1)	4 (1.2)	0	0	0	0
Myositis	3 (0.9)	2 (0.6)	0	0	0	0
Arthralgia	1 (0.3)	0	0	0	0	0
Autoimmune myositis	1 (0.3)	1 (0.3)	0	0	0	0
Hypercreatinemia	1 (0.3)	0	0	0	0	0
Polymyalgia rheumatica	1 (0.3)	1 (0.3)	0	0	0	0
Endocrine disorders	6 (1.8)	3 (0.9)	0	0	0	0
Adrenal insufficiency	3 (0.9)	1 (0.3)	0	0	0	0
Lymphocytic hypophysitis	2 (0.6)	2 (0.6)	0	0	0	0
Hypophysitis	1 (0.3)	0	0	0	0	0
Cardiac disorders	4 (1.2)	2 (0.6)	0	3 (0.9)	3 (0.9)	0
Myocarditis	2 (0.6)	1 (0.3)	0	0	0	0
Autoimmune myocarditis	1 (0.3)	1 (0.3)	0	0	0	0
Cardiac failure	1 (0.3)	0	0	1 (0.3)	1 (0.3)	0
Coronary artery stenosis	0	0	0	1 (0.3)	1 (0.3)	0
Myocardial infarction	0	0	0	1 (0.3)	1 (0.3)	0
Nervous system disorders	4 (1.2)	4 (1.2)	0	7 (2.2)	2 (0.6)	0
Autonomic nervous system imbalance	1 (0.3)	1 (0.3)	0	0	0	0
Encephalopathy	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0

MedDRA Version: 26.1

CTCAE Version 5.0

Includes events reported between first dose and 30 days after last dose of study therapy.

Program Source: /projects/bms247812/stats/interim/prog/tables/rt-ae-cat.sas

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Table 14.3.2.3.1.1
Adverse Events Leading to Discontinuation Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N = 332			Sora / Lenva N = 325		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Neurotoxicity	1 (0.3)	1 (0.3)	0	0	0	0
Peripheral sensorimotor neuropathy	1 (0.3)	1 (0.3)	0	0	0	0
Cerebral haematoma	0	0	0	1 (0.3)	0	0
Cerebrovascular accident	0	0	0	1 (0.3)	0	0
Hepatic encephalopathy	0	0	0	2 (0.6)	1 (0.3)	0
Hypoxic-ischaemic encephalopathy	0	0	0	1 (0.3)	0	0
Posterior reversible encephalopathy syndrome	0	0	0	1 (0.3)	1 (0.3)	0
Respiratory, thoracic and mediastinal disorders	4 (1.2)	3 (0.9)	0	2 (0.6)	1 (0.3)	0
Pneumonitis	2 (0.6)	1 (0.3)	0	0	0	0
Dyspnoea	1 (0.3)	1 (0.3)	0	0	0	0
Haemoptysis	1 (0.3)	1 (0.3)	0	0	0	0
Epiglottic oedema	0	0	0	1 (0.3)	1 (0.3)	0
Epistaxis	0	0	0	1 (0.3)	0	0
Skin and subcutaneous tissue disorders	4 (1.2)	3 (0.9)	0	4 (1.2)	2 (0.6)	0
Psoriasis	2 (0.6)	1 (0.3)	0	0	0	0
Drug eruption	1 (0.3)	1 (0.3)	0	0	0	0
Stevens-Johnson syndrome	1 (0.3)	1 (0.3)	0	0	0	0
Diabetic foot	0	0	0	1 (0.3)	0	0
Rash	0	0	0	2 (0.6)	1 (0.3)	0
Toxic skin eruption	0	0	0	1 (0.3)	1 (0.3)	0
Blood and lymphatic system disorders	3 (0.9)	2 (0.6)	0	0	0	0
Autoimmune haemolytic anaemia	2 (0.6)	1 (0.3)	0	0	0	0
Leukopenia	1 (0.3)	1 (0.3)	0	0	0	0

MedDRA Version: 26.1

CTCAE Version 5.0

Includes events reported between first dose and 30 days after last dose of study therapy.

Program Source: /projects/bms247812/stats/interim/prog/tables/rt-ae-cat.sas

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Table 14.3.2.3.1.1
Adverse Events Leading to Discontinuation Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N = 332			Sora / Lenva N = 325		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Neutropenia	1 (0.3)	1 (0.3)	0	0	0	0
General disorders and administration site conditions	3 (0.9)	3 (0.9)	0	5 (1.5)	2 (0.6)	0
General physical health deterioration	1 (0.3)	1 (0.3)	0	0	0	0
Multiple organ dysfunction syndrome	1 (0.3)	1 (0.3)	0	0	0	0
Oedema peripheral	1 (0.3)	1 (0.3)	0	1 (0.3)	1 (0.3)	0
Asthenia	0	0	0	4 (1.2)	1 (0.3)	0
Renal and urinary disorders	2 (0.6)	0	0	7 (2.2)	4 (1.2)	0
Acute kidney injury	1 (0.3)	0	0	1 (0.3)	1 (0.3)	0
Renal failure	1 (0.3)	0	0	0	0	0
Nephrotic syndrome	0	0	0	2 (0.6)	2 (0.6)	0
Proteinuria	0	0	0	5 (1.5)	2 (0.6)	0
Eye disorders	1 (0.3)	1 (0.3)	0	0	0	0
Idiopathic orbital inflammation	1 (0.3)	1 (0.3)	0	0	0	0
Immune system disorders	1 (0.3)	1 (0.3)	0	0	0	0
Hypersensitivity	1 (0.3)	1 (0.3)	0	0	0	0
Injury, poisoning and procedural complications	1 (0.3)	1 (0.3)	0	0	0	0
Femur fracture	1 (0.3)	1 (0.3)	0	0	0	0
Metabolism and nutrition disorders	1 (0.3)	1 (0.3)	0	2 (0.6)	0	0
Decreased appetite	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0
Hyperkalaemia	0	0	0	1 (0.3)	0	0

MedDRA Version: 26.1

CTCAE Version 5.0

Includes events reported between first dose and 30 days after last dose of study therapy.

Program Source: /projects/bms247812/stats/interim/prog/tables/rt-ae-cat.sas

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Table 14.3.2.3.1.1
Adverse Events Leading to Discontinuation Summary
by Worst CTC Grade (Any Grade, Grade 3-4, Grade 5)
All Treated Subjects

System Organ Class (%) Preferred Term (%)	Nivo + Ipi N = 332			Sora / Lenva N = 325		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Vascular disorders	0	0	0	2 (0.6)	2 (0.6)	0
Arterial haemorrhage	0	0	0	1 (0.3)	1 (0.3)	0
Hypertensive crisis	0	0	0	1 (0.3)	1 (0.3)	0

MedDRA Version: 26.1
CTCAE Version 5.0
Includes events reported between first dose and 30 days after last dose of study therapy.
Program Source: /projects/bms247812/stats/interim/prog/tables/rt-ae-cat.sas

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Table 14.3.2.4.6
Immune-Mediated Adverse Events Definition

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

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Table 14.3.2.4.6
Immune-Mediated Adverse Events Definition

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

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Protocol: CA2099DW

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Table 14.3.2.4.6
Immune-Mediated Adverse Events Definition

Category	Preferred Terms
HYPOTHYROIDISM/THYROIDITIS	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 Creatinine renal clearance decreased End stage renal disease Glomerulonephritis rapidly progressive Hypercreatininaemia Immune-mediated nephritis Immune-mediated renal disorder Nephritis Nephritis allergic Paraneoplastic glomerulonephritis Renal failure Renal tubular necrosis Subacute kidney injury Tubulointerstitial nephritis
PNEUMONITIS	Hypersensitivity pneumonitis Idiopathic interstitial pneumonia Immune-mediated lung disease Interstitial lung disease Pneumonitis
RASH	Autoimmune blistering disease Autoimmune dermatitis Bullous haemorrhagic dermatosis

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Table 14.3.2.4.6
Immune-Mediated Adverse Events Definition

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Category	Preferred Terms
RASH	Dermatitis Dermatitis acneiform Dermatitis allergic Dermatitis atopic Dermatitis exfoliative Drug eruption Erythema multiforme Erythrodermic atopic dermatitis Exfoliative rash Fixed eruption Immune-mediated dermatitis Lichen planus pemphigoides Mucocutaneous disorder Mucosa vesicle Mucous membrane pemphigoid Nodular rash Pemphigoid Pemphigus Pustule Rash Rash erythematous Rash macular Rash maculo-papular Rash morbilliform Rash papular Rash pruritic Rash pustular Rash vesicular Scrotal dermatitis Severe cutaneous adverse reaction Stevens-Johnson syndrome Toxic epidermal necrolysis Toxic skin eruption Urticarial dermatitis

MedDRA Version: 26.1
Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Table 14.3.2.4.6
Immune-Mediated Adverse Events Definition

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Category	Preferred Terms
THYROIDITIS	Atrophic thyroiditis Autoimmune thyroiditis Immune-mediated thyroiditis Silent thyroiditis Thyroiditis Thyroiditis acute

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Table 9.1.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
All Treated Subjects

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH ANY IMMUNE-MEDIATED ADVERSE EVENTS (IMAE)	332	191 (57.5)	2.83 (2.17, 4.30)	325	14 (4.3)	N.A.	20.64 (11.97, 35.59)	<0.0001*
SUBJECTS WITH PNEUMONITIS	332	7 (2.1)	N.A.	325	0	N.E.	N.E.	0.0082*
SUBJECTS WITH DIARRHEA/COLITIS	332	28 (8.4)	N.A.	325	1 (0.3)	N.A.	29.77 (4.05, >99.99)	<0.0001*
SUBJECTS WITH HEPATITIS	332	63 (19.0)	N.A.	325	0	N.E.	N.E.	<0.0001*
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION	332	5 (1.5)	N.A.	325	0	N.E.	N.E.	0.0222*
SUBJECTS WITH RASH	332	51 (15.4)	N.A.	325	2 (0.6)	N.A.	27.69 (6.74, >99.99)	<0.0001*
SUBJECTS WITH HYPERSENSITIVITY	332	4 (1.2)	N.A.	325	0	N.E.	N.E.	0.0464*
SUBJECTS WITH ADRENAL INSUFFICIENCY	332	18 (5.4)	N.A.	325	0	N.E.	N.E.	<0.0001*
SUBJECTS WITH HYPOTHYROIDISM/THYROIDITIS	332	62 (18.7)	N.A.	325	11 (3.4)	N.A.	6.42 (3.38, 12.21)	<0.0001*
SUBJECTS WITH HYPOTHYROIDISM	332	46 (13.9)	N.A.	325	11 (3.4)	N.A.	4.75 (2.46, 9.19)	<0.0001*
SUBJECTS WITH THYROIDITIS	332	18 (5.4)	N.A.	325	0	N.E.	N.E.	<0.0001*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.1.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
All Treated Subjects

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH DIABETES MELLITUS	332	2 (0.6)	N.A.	325	0	N.E.	N.E.	0.1717
SUBJECTS WITH HYPERTHYROIDISM	332	36 (10.8)	N.A.	325	0	N.E.	N.E.	<0.0001*
SUBJECTS WITH HYPOPHYSITIS	332	9 (2.7)	N.A.	325	0	N.E.	N.E.	0.0023*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),
Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein
(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteimae-ebr2618.sas

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Table 9.1.2
Time to Event Analyses of Immune Medicated AE Categories for Severe TEAE (Grade >=3)
All Treated Subjects

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH SEVERE IMMUNE-MEDIATED ADVERSE EVENTS (IMAE)	332	93 (28.0)	N.A.	325	2 (0.6)	N.A.	52.79 (13.01, >99.99)	<0.0001*
SUBJECTS WITH PNEUMONITIS	332	3 (0.9)	N.A.	325	0	N.E.	N.E.	0.1225
SUBJECTS WITH DIARRHEA/COLITIS	332	15 (4.5)	N.A.	325	1 (0.3)	N.A.	15.56 (2.06, >99.99)	0.0004*
SUBJECTS WITH HEPATITIS	332	51 (15.4)	N.A.	325	0	N.E.	N.E.	<0.0001*
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION	332	3 (0.9)	N.A.	325	0	N.E.	N.E.	0.0763
SUBJECTS WITH RASH	332	14 (4.2)	N.A.	325	1 (0.3)	N.A.	14.21 (1.87, >99.99)	0.0007*
SUBJECTS WITH HYPERSENSITIVITY	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH ADRENAL INSUFFICIENCY	332	6 (1.8)	N.A.	325	0	N.E.	N.E.	0.0098*
SUBJECTS WITH HYPOTHYROIDISM/THYROIDITIS	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3237
SUBJECTS WITH HYPOTHYROIDISM	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH THYROIDITIS	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3237

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

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Table 9.1.2
Time to Event Analyses of Immune Medicated AE Categories for Severe TEAE (Grade >=3)
All Treated Subjects

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH DIABETES MELLITUS	332	2 (0.6)	N.A.	325	0	N.E.	N.E.	0.1717
SUBJECTS WITH HYPERTHYROIDISM	332	2 (0.6)	N.A.	325	0	N.E.	N.E.	0.1703
SUBJECTS WITH HYPOPHYSITIS	332	4 (1.2)	N.A.	325	0	N.E.	N.E.	0.0439*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteimae-ibr2618.sas

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Table 9.1.3
Time to Event Analyses of Immune Medicated AE Categories for Serious TEAE
All Treated Subjects

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH SERIOUS IMMUNE-MEDIATED ADVERSE EVENTS (IMAE)	332	70 (21.1)	N.A.	325	1 (0.3)	N.A.	77.15 (10.71, >99.99)	<0.0001*
SUBJECTS WITH PNEUMONITIS	332	4 (1.2)	N.A.	325	0	N.E.	N.E.	0.0661
SUBJECTS WITH DIARRHEA/COLITIS	332	17 (5.1)	N.A.	325	0	N.E.	N.E.	<0.0001*
SUBJECTS WITH HEPATITIS	332	27 (8.1)	N.A.	325	0	N.E.	N.E.	<0.0001*
SUBJECTS WITH NEPHRITIS AND RENAL DYSFUNCTION	332	4 (1.2)	N.A.	325	0	N.E.	N.E.	0.0425*
SUBJECTS WITH RASH	332	6 (1.8)	N.A.	325	1 (0.3)	N.A.	5.77 (0.69, 47.90)	0.0661
SUBJECTS WITH HYPERSENSITIVITY	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3237
SUBJECTS WITH ADRENAL INSUFFICIENCY	332	7 (2.1)	N.A.	325	0	N.E.	N.E.	0.0047*
SUBJECTS WITH HYPOTHYROIDISM/THYROIDITIS	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3237
SUBJECTS WITH HYPOTHYROIDISM	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH THYROIDITIS	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3237
SUBJECTS WITH DIABETES MELLITUS	332	0	N.E.	325	0	N.E.	N.E.	N.E.

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

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Table 9.1.3
Time to Event Analyses of Immune Medicated AE Categories for Serious TEAE
All Treated Subjects

Immune-Mediated Adverse Events (IMAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH HYPERTHYROIDISM	332	2 (0.6)	N.A.	325	0	N.E.	N.E.	0.1703
SUBJECTS WITH HYPOPHYSITIS	332	4 (1.2)	N.A.	325	0	N.E.	N.E.	0.0439*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.
(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),
Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein
(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
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Table 14.3.2.4.11
Other Events of Special Interest Definition

Category	Preferred Terms
AUTOIMMUNE CYTOPENIA	Antiphospholipid syndrome Autoimmune anaemia Autoimmune aplastic anaemia Autoimmune haemolytic anaemia Autoimmune heparin-induced thrombocytopenia Autoimmune neutropenia Autoimmune pancytopenia Cold type haemolytic anaemia Coombs positive haemolytic anaemia Evans syndrome Idiopathic CD4 lymphocytopenia Immune thrombocytopenia Immune-mediated cytopenia Immune-mediated pancytopenia Pernicious anaemia Warm autoimmune haemolytic anaemia
AUTOIMMUNE EYE DISORDER	Autoimmune eye disorder Autoimmune retinopathy
DEMYELINATION EVENT	Anti-myelin-associated glycoprotein associated polyneuropathy Demyelinating polyneuropathy Demyelination Immune-mediated myelitis Immune-mediated optic neuritis
ENCEPHALITIS EVENT	Acute disseminated encephalomyelitis Acute encephalitis with refractory, repetitive partial seizures Autoimmune encephalopathy Bickerstaff's encephalitis Encephalitis Encephalitis allergic Encephalitis autoimmune Encephalitis brain stem Encephalitis haemorrhagic

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Table 14.3.2.4.11
Other Events of Special Interest Definition

Category	Preferred Terms
ENCEPHALITIS EVENT	Encephalitis lethargica Encephalitis toxic Immune effector cell-associated neurotoxicity syndrome Immune-mediated encephalitis Immune-mediated encephalopathy 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 eye Acute graft versus host disease in intestine Acute graft versus host disease in liver Acute graft versus host disease in skin Acute graft versus host disease oral Chronic graft versus host disease Chronic graft versus host disease in eye Chronic graft versus host disease in intestine Chronic graft versus host disease in liver Chronic graft versus host disease in lung Chronic graft versus host disease in skin Chronic graft versus host disease oral Graft versus host disease Graft versus host disease in eye Graft versus host disease in gastrointestinal tract Graft versus host disease in liver Graft versus host disease in lung Graft versus host disease in skin Graft versus host disease oral
GUILLAIN-BARRE SYNDROME	Ascending flaccid paralysis Guillain-Barre syndrome Miller Fisher syndrome

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Table 14.3.2.4.11
Other Events of Special Interest Definition

Category	Preferred Terms
IMMUNE MEDIATED ARTHRITIS	Acute aseptic arthritis Autoimmune arthritis Immune-mediated arthritis
MYASTHENIC SYNDROME	Immune-mediated myasthenia gravis Myasthenia gravis Myasthenia gravis crisis Myasthenic syndrome Ocular myasthenia
MYOCARDITIS EVENT	Autoimmune myocarditis Eosinophilic myocarditis Giant cell myocarditis Hypersensitivity myocarditis Immune-mediated myocarditis Myocarditis Myopericarditis
MYOSITIS/RHABDOMYOLYSIS EVENT	Autoimmune myositis Dermatomyositis Immune-mediated myositis Inclusion body myositis Myositis Necrotising myositis Paraneoplastic dermatomyositis Polymyositis Rhabdomyolysis
PANCREATITIS EVENT	Autoimmune pancreatitis Haemorrhagic necrotic pancreatitis Immune-mediated pancreatitis Pancreatitis Pancreatitis acute Pancreatitis necrotising Subacute pancreatitis

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Table 14.3.2.4.11
Other Events of Special Interest Definition

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Category	Preferred Terms
UVEITIS EVENT	Autoimmune uveitis Chorioretinitis Cyclitis Immune recovery uveitis Immune-mediated uveitis Iridocyclitis Iritis Keratouveitis Uveitis Vogt-Koyanagi-Harada disease

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Table 10.1.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH ANY OTHER EVENTS OF SPECIAL INTEREST (OESI)	332	16 (4.8)	N.A.	325	3 (0.9)	N.A.	5.52 (1.60, 19.04)	0.0024*
SUBJECTS WITH MYASTHENIC SYNDROME	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3302
SUBJECTS WITH DEMYELINATION EVENT	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3306
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	332	9 (2.7)	N.A.	325	2 (0.6)	N.A.	4.45 (0.95, 20.80)	0.0385*
SUBJECTS WITH UVEITIS EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	332	3 (0.9)	N.A.	325	0	N.E.	N.E.	0.0867
SUBJECTS WITH MYOSITIS/RHABDOMYOLYSIS EVENT	332	4 (1.2)	N.A.	325	1 (0.3)	N.A.	4.33 (0.48, 38.93)	0.1546
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH AUTOIMMUNE CYTOPENIA	332	2 (0.6)	N.A.	325	0	N.E.	N.E.	0.1643
SUBJECTS WITH AUTOIMMUNE EYE DISORDER	332	0	N.E.	325	0	N.E.	N.E.	N.E.

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

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Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.1.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH IMMUNE MEDIATED ARTHRITIS	332	0	N.E.	325	0	N.E.	N.E.	N.E.

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.
(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),
Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein
(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
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Table 10.1.2
Time to Event Analyses of Other Events of Special Interest for Severe TEAE (Grade >=3)
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH SEVERE OTHER EVENTS OF SPECIAL INTEREST (OESI)	332	9 (2.7)	N.A.	325	3 (0.9)	N.A.	2.94 (0.79, 10.99)	0.0931
SUBJECTS WITH MYASTHENIC SYNDROME	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3340
SUBJECTS WITH DEMYELINATION EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	332	4 (1.2)	N.A.	325	2 (0.6)	N.A.	1.76 (0.31, 9.95)	0.5160
SUBJECTS WITH UVEITIS EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	332	2 (0.6)	N.A.	325	0	N.E.	N.E.	0.1643
SUBJECTS WITH MYOSITIS/RHABDOMYOLYSIS EVENT	332	3 (0.9)	N.A.	325	1 (0.3)	N.A.	3.30 (0.34, 31.99)	0.2756
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH AUTOIMMUNE CYTOPENIA	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3207
SUBJECTS WITH AUTOIMMUNE EYE DISORDER	332	0	N.E.	325	0	N.E.	N.E.	N.E.

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

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Table 10.1.2
Time to Event Analyses of Other Events of Special Interest for Severe TEAE (Grade >=3)
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH IMMUNE MEDIATED ARTHRITIS	332	0	N.E.	325	0	N.E.	N.E.	N.E.

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.
(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),
Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein
(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
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Table 10.1.3
Time to Event Analyses of Other Events of Special Interest for Serious TEAE
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH SERIOUS OTHER EVENTS OF SPECIAL INTEREST (OESI)	332	9 (2.7)	N.A.	325	3 (0.9)	N.A.	2.91 (0.78, 10.87)	0.0967
SUBJECTS WITH MYASTHENIC SYNDROME	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3340
SUBJECTS WITH DEMYELINATION EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH GUILLAIN-BARRE SYNDROME	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH PANCREATITIS EVENT	332	2 (0.6)	N.A.	325	2 (0.6)	N.A.	0.75 (0.10, 5.74)	0.7791
SUBJECTS WITH UVEITIS EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH ENCEPHALITIS EVENT	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH MYOCARDITIS EVENT	332	3 (0.9)	N.A.	325	0	N.E.	N.E.	0.0867
SUBJECTS WITH MYOSITIS/RHABDOMYOLYSIS EVENT	332	4 (1.2)	N.A.	325	1 (0.3)	N.A.	4.33 (0.48, 38.93)	0.1546
SUBJECTS WITH GRAFT VERSUS HOST DISEASE	332	0	N.E.	325	0	N.E.	N.E.	N.E.
SUBJECTS WITH AUTOIMMUNE CYTOPENIA	332	2 (0.6)	N.A.	325	0	N.E.	N.E.	0.1643
SUBJECTS WITH AUTOIMMUNE EYE DISORDER	332	0	N.E.	325	0	N.E.	N.E.	N.E.

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteoesi-ibr2618.sas

26FEB2025:05:19:12

Protocol: CA209-9DW

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Table 10.1.3
Time to Event Analyses of Other Events of Special Interest for Serious TEAE
All Treated Subjects

Other Events of Special Interest (OESI)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH IMMUNE MEDIATED ARTHRITIS	332	0	N.E.	325	0	N.E.	N.E.	N.E.

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.
(1) KME of median time to first AE.
(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.
(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),
Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein
(AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
Program Name: rt-ae-tteoesi-ebr2618.sas

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Protocol: CA2099DW

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Table 14.3.2.4.1
Select Adverse Events Definition

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

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

20MAR2024:05:01:04

Protocol: CA2099DW

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Table 14.3.2.4.1
Select Adverse Events Definition

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

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Table 14.3.2.4.1
Select Adverse Events Definition

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

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Protocol: CA2099DW

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Table 14.3.2.4.1
Select Adverse Events Definition

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

MedDRA Version: 26.1

Program Source: /pic/projects2/blinded/bms247812/stats/interim/prog/listings/rl-ae-slaedef.sas

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Protocol: CA2099DW

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Table 14.3.2.4.1
Select Adverse Events Definition

Category	Subcategory	Preferred Terms
SKIN ADVERSE EVENT		Dermatitis Dermatitis acneiform Dermatitis allergic Dermatitis atopic Dermatitis exfoliative Drug eruption Eczema Erythema Erythema multiforme Erythrodermic atopic dermatitis Exfoliative rash Fixed eruption Generalised bullous fixed drug eruption Guttate psoriasis Immune-mediated dermatitis Lichen planus pemphigoides Mucocutaneous disorder Mucosa vesicle Mucous membrane pemphigoid 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

Protocol: CA2099DW

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Table 14.3.2.4.1
Select Adverse Events Definition

Category	Subcategory	Preferred Terms
SKIN ADVERSE EVENT		Rash papular Rash pruritic Rash pustular Rash vesicular SJS-TEN overlap Scrotal dermatitis Severe cutaneous adverse reaction Skin exfoliation Skin hypopigmentation Skin irritation Stevens-Johnson syndrome Toxic epidermal necrolysis Toxic skin eruption Urticaria Urticarial dermatitis Vitiligo Vulval eczema

Protocol: CA209-9DW

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Table 8.1.1
Time to Event Analyses of Select AE Categories for Any TEAE
All Treated Subjects

Select Adverse Events (SLAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH ANY SELECT ADVERSE EVENTS (SLAE)	332	303 (91.3)	0.72 (0.69, 0.72)	325	269 (82.8)	1.35 (0.85, 1.41)	1.65 (1.39, 1.96)	<0.0001*
SUBJECTS WITH ENDOCRINE ADVERSE EVENTS	332	111 (33.4)	N.A. (24.57, N.A.)	325	116 (35.7)	N.A.	0.93 (0.72, 1.21)	0.6106
SUBJECTS WITH GASTROINTESTINAL ADVERSE EVENTS	332	88 (26.5)	N.A.	325	133 (40.9)	14.65 (11.24, 20.76)	0.62 (0.47, 0.81)	0.0004*
SUBJECTS WITH HEPATIC ADVERSE EVENTS	332	175 (52.7)	4.83 (2.79, 13.37)	325	98 (30.2)	N.A.	2.31 (1.80, 2.96)	<0.0001*
SUBJECTS WITH PULMONARY ADVERSE EVENTS	332	13 (3.9)	N.A.	325	2 (0.6)	N.A.	6.59 (1.48, 29.35)	0.0044*
SUBJECTS WITH RENAL ADVERSE EVENTS	332	30 (9.0)	N.A.	325	25 (7.7)	43.47 (N.A., N.A.)	1.28 (0.74, 2.19)	0.3736
SUBJECTS WITH SKIN ADVERSE EVENTS	332	209 (63.0)	1.64 (1.25, 2.14)	325	159 (48.9)	9.69 (5.45, 24.80)	1.71 (1.39, 2.11)	<0.0001*
SUBJECTS WITH HYPERSENSITIVITY/INFUSION REACTIONS	332	8 (2.4)	N.A.	325	1 (0.3)	N.A.	7.88 (0.98, 62.99)	0.0209*

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC), Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein (AFP) (< 400 ng/mL or >= 400 ng/mL) as entered into IRT (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteslae-ebr2618.sas

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Protocol: CA209-9DW

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Table 8.1.2
Time to Event Analyses of Select AE Categories for Severe TEAE (Grade ≥3)
All Treated Subjects

Select Adverse Events (SLAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH SEVERE SELECT ADVERSE EVENTS (SLAE)	332	130 (39.2)	N.A. (20.44, N.A.)	325	69 (21.2)	N.A.	2.12 (1.58, 2.84)	<0.0001*
SUBJECTS WITH ENDOCRINE ADVERSE EVENTS	332	14 (4.2)	N.A.	325	0	N.E.	N.E.	0.0001*
SUBJECTS WITH GASTROINTESTINAL ADVERSE EVENTS	332	20 (6.0)	N.A.	325	12 (3.7)	N.A.	1.78 (0.87, 3.64)	0.1103
SUBJECTS WITH HEPATIC ADVERSE EVENTS	332	80 (24.1)	N.A.	325	33 (10.2)	N.A.	2.62 (1.75, 3.94)	<0.0001*
SUBJECTS WITH PULMONARY ADVERSE EVENTS	332	4 (1.2)	N.A.	325	1 (0.3)	N.A.	3.50 (0.39, 31.51)	0.2342
SUBJECTS WITH RENAL ADVERSE EVENTS	332	10 (3.0)	N.A.	325	7 (2.2)	N.A.	1.45 (0.55, 3.84)	0.4473
SUBJECTS WITH SKIN ADVERSE EVENTS	332	21 (6.3)	N.A.	325	21 (6.5)	N.A.	0.98 (0.53, 1.80)	0.9421
SUBJECTS WITH HYPERSENSITIVITY/INFUSION REACTIONS	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3014

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or ≥ 400 ng/mL) as entered into IRT (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteslae-ebr2618.sas

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Protocol: CA209-9DW

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Table 8.1.3
Time to Event Analyses of Select AE Categories for Serious TEAE
All Treated Subjects

Select Adverse Events (SLAE)	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2)	P-value (3)
SUBJECTS WITH SERIOUS SELECT ADVERSE EVENTS (SLAE)	332	88 (26.5)	N.A.	325	24 (7.4)	N.A.	4.05 (2.57, 6.36)	<0.0001*
SUBJECTS WITH ENDOCRINE ADVERSE EVENTS	332	13 (3.9)	N.A.	325	0	N.E.	N.E.	0.0002*
SUBJECTS WITH GASTROINTESTINAL ADVERSE EVENTS	332	17 (5.1)	N.A.	325	2 (0.6)	N.A.	9.02 (2.08, 39.04)	0.0004*
SUBJECTS WITH HEPATIC ADVERSE EVENTS	332	40 (12.0)	N.A.	325	13 (4.0)	N.A.	3.19 (1.71, 5.97)	0.0001*
SUBJECTS WITH PULMONARY ADVERSE EVENTS	332	5 (1.5)	N.A.	325	1 (0.3)	N.A.	4.48 (0.52, 38.54)	0.1348
SUBJECTS WITH RENAL ADVERSE EVENTS	332	11 (3.3)	N.A.	325	7 (2.2)	N.A.	1.60 (0.62, 4.15)	0.3268
SUBJECTS WITH SKIN ADVERSE EVENTS	332	10 (3.0)	N.A.	325	4 (1.2)	N.A.	2.32 (0.72, 7.45)	0.1469
SUBJECTS WITH HYPERSENSITIVITY/INFUSION REACTIONS	332	1 (0.3)	N.A.	325	0	N.E.	N.E.	0.3237

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

HR = hazard ratio; KME = Kaplan-Meier estimate; N.E. = Not estimable.

(1) KME of median time to first AE.

(2) Stratified Cox proportional hazard model. HR is Nivolumab + Ipilimumab over Sorafenib / Lenvatinib.

(3) p-value from log-rank test stratified by Etiology (viral related-HCC vs non-viral related-HCC),

Vascular invasion and/or extrahepatic spread (present or absent), Baseline alpha-fetoprotein

(AFP) (< 400 ng/mL or ≥ 400 ng/mL) as entered into IRT (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteslae-ebr2618.sas

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Protocol: CA209-9DW

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Table 2
Overall Survival
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
OVERALL	335	194 (57.9)	23.66 (18.83, 29.44)	333	228 (68.5)	20.63 (17.48, 22.54)	0.79 (0.65, 0.96)	0.0159	
AGE									0.8799
< 65	162	88 (54.3)	26.81 (22.97, 32.99)	149	98 (65.8)	22.74 (19.12, 26.15)	0.78 (0.58, 1.04)	0.0855	
>= 65	173	106 (61.3)	18.83 (15.67, 27.14)	184	130 (70.7)	18.17 (15.64, 21.45)	0.81 (0.63, 1.05)	0.1179	
SEX									0.2228
MALE	271	162 (59.8)	22.97 (17.87, 29.31)	277	190 (68.6)	21.06 (17.84, 22.97)	0.83 (0.68, 1.03)	0.0905	
FEMALE	64	32 (50.0)	26.87 (19.61, N.A.)	56	38 (67.9)	17.25 (11.60, 23.29)	0.63 (0.39, 1.00)	0.0493	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

Feb 2024 DBL

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ossb-ebr2618.sas

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Protocol: CA209-9DW

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Table 2
Overall Survival
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.2161
HBV	99	57 (57.6)	23.20 (16.00, 34.00)	98	61 (62.2)	22.74 (19.78, 27.60)	0.95 (0.66, 1.36)	0.7631	
HCV	27	17 (63.0)	16.20 (4.60, 32.56)	27	17 (63.0)	17.84 (11.83, 28.85)	1.16 (0.59, 2.27)	0.6748	
UNINFECTED	209	120 (57.4)	25.76 (18.83, 32.99)	208	150 (72.1)	17.91 (15.54, 22.01)	0.70 (0.55, 0.89)	0.0034	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.9102
PRESENT	205	126 (61.5)	19.38 (16.33, 25.86)	204	147 (72.1)	17.74 (14.65, 21.06)	0.79 (0.62, 1.00)	0.0488	
ABSENT	130	68 (52.3)	29.31 (22.54, 37.82)	129	81 (62.8)	22.90 (20.27, 29.14)	0.78 (0.57, 1.08)	0.1388	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

Feb 2024 DBL

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ossup-ebr2618.sas

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Protocol: CA209-9DW

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Table 2
Overall Survival
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)			Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)			
BASELINE									0.2032
ALPHA-FETOPROTEIN									
< 400 NG/ML	225	122 (54.2)	25.86 (21.98, 33.48)	222	141 (63.5)	23.66 (20.76, 28.62)	0.85 (0.66, 1.08)	0.1801	
>= 400 NG/ML	110	72 (65.5)	16.43 (10.61, 27.89)	111	87 (78.4)	12.68 (9.56, 16.82)	0.70 (0.51, 0.97)	0.0297	

(a) Hazard ratio from unstratified Cox proportional hazard model.
(b) p-value from unstratified log-rank test.
(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
Feb 2024 DBL
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
Program Name: rt-ef-ossup-ubr2618.sas

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Protocol: CA209-9DW

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Table 5.1
Time to First Meaningful Deterioration
EQ-5D-3L-VAS
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
OVERALL	335	116 (34.6)	18.96 (7.56, N.A.)	333	155 (46.5)	5.78 (4.60, 7.46)	0.67 (0.53, 0.86)	0.0012	
AGE									0.2449
< 65	162	50 (30.9)	N.A. (12.39, N.A.)	149	67 (45.0)	7.39 (3.75, 10.02)	0.59 (0.41, 0.85)	0.0041	
>= 65	173	66 (38.2)	7.56 (4.44, 24.87)	184	88 (47.8)	4.93 (3.09, 7.52)	0.78 (0.57, 1.07)	0.1274	
SEX									0.5127
MALE	271	97 (35.8)	21.26 (5.59, N.A.)	277	130 (46.9)	5.78 (4.60, 7.62)	0.70 (0.54, 0.91)	0.0077	
FEMALE	64	19 (29.7)	18.96 (5.55, N.A.)	56	25 (44.6)	6.47 (1.54, N.A.)	0.56 (0.30, 1.01)	0.0515	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

Feb 2024 DBL

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 15 points decrease from baseline) in the EuroQoL 5-dimension quality-of-life 3-level version (EQ-5D-3L) visual assessment scale (VAS)

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-ebr2618.sas

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Protocol: CA209-9DW

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Table 5.1
Time to First Meaningful Deterioration
EQ-5D-3L-VAS
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.5696
HBV	99	25 (25.3)	N.A. (12.39, N.A.)	98	43 (43.9)	7.39 (3.75, 14.98)	0.57 (0.35, 0.93)	0.0225	
HCV	27	7 (25.9)	N.A. (4.63, N.A.)	27	13 (48.1)	6.64 (2.56, N.A.)	0.49 (0.19, 1.22)	0.1203	
UNINFECTED	209	84 (40.2)	11.50 (4.44, N.A.)	208	99 (47.6)	4.83 (3.09, 7.46)	0.73 (0.54, 0.98)	0.0333	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.2448
PRESENT	205	68 (33.2)	21.26 (5.55, N.A.)	204	85 (41.7)	7.39 (4.60, 10.74)	0.75 (0.54, 1.04)	0.0777	
ABSENT	130	48 (36.9)	12.39 (5.59, N.A.)	129	70 (54.3)	4.67 (2.83, 7.46)	0.58 (0.40, 0.83)	0.0031	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

Feb 2024 DBL

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 15 points decrease from baseline) in the EuroQoL 5-dimension quality-of-life 3-level version (EQ-5D-3L) visual assessment scale (VAS)

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.1
Time to First Meaningful Deterioration
EQ-5D-3L-VAS
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE ALPHA-FETOPROTEIN									0.7856
< 400 NG/ML	225	82 (36.4)	12.62 (5.59, N.A.)	222	113 (50.9)	5.55 (3.75, 7.46)	0.65 (0.49, 0.87)	0.0036	
>= 400 NG/ML	110	34 (30.9)	N.A. (5.55, N.A.)	111	42 (37.8)	5.78 (3.75, N.A.)	0.73 (0.47, 1.16)	0.1732	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

Feb 2024 DBL

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 15 points decrease from baseline) in the EuroQoL 5-dimension quality-of-life 3-level version (EQ-5D-3L) visual assessment scale (VAS)

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.8
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Total Score
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
OVERALL	335	95 (28.4)	N.A. (23.52, N.A.)	333	129 (38.7)	9.00 (6.54, 14.98)	0.69 (0.52, 0.89)	0.0051	
AGE									0.4824
< 65	162	41 (25.3)	N.A. (32.16, N.A.)	149	51 (34.2)	10.61 (7.46, N.A.)	0.64 (0.42, 0.96)	0.0304	
>= 65	173	54 (31.2)	23.52 (5.72, N.A.)	184	78 (42.4)	6.93 (4.83, 12.29)	0.76 (0.54, 1.08)	0.1317	
SEX									0.7762
MALE	271	77 (28.4)	32.16 (13.37, N.A.)	277	107 (38.6)	10.38 (6.54, 14.98)	0.69 (0.51, 0.93)	0.0128	
FEMALE	64	18 (28.1)	N.A. (4.57, N.A.)	56	22 (39.3)	8.87 (2.27, N.A.)	0.66 (0.35, 1.23)	0.1830	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 27 points decrease from baseline) in the Total Score of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.8
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Total Score
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.3901
HBV	99	23 (23.2)	N.A. (9.07, N.A.)	98	31 (31.6)	14.98 (7.36, N.A.)	0.83 (0.48, 1.42)	0.4878	
HCV	27	5 (18.5)	N.A. (12.29, N.A.)	27	14 (51.9)	6.93 (2.79, N.A.)	0.35 (0.13, 0.99)	0.0378	
UNINFECTED	209	67 (32.1)	32.16 (8.74, N.A.)	208	84 (40.4)	8.87 (4.83, 12.29)	0.67 (0.49, 0.93)	0.0168	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.6467
PRESENT	205	56 (27.3)	N.A. (23.52, N.A.)	204	78 (38.2)	8.25 (5.55, 14.98)	0.65 (0.46, 0.92)	0.0147	
ABSENT	130	39 (30.0)	32.16 (8.08, N.A.)	129	51 (39.5)	10.38 (6.93, N.A.)	0.74 (0.49, 1.13)	0.1664	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 27 points decrease from baseline) in the Total Score of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-ebr2618.sas

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Protocol: CA209-9DW

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Table 5.8
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Total Score
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE									0.6751
ALPHA-FETOPROTEIN									
< 400 NG/ML	225	62 (27.6)	32.16 (23.52, N.A.)	222	88 (39.6)	11.10 (6.54, N.A.)	0.71 (0.51, 0.98)	0.0374	
>= 400 NG/ML	110	33 (30.0)	N.A. (6.54, N.A.)	111	41 (36.9)	8.25 (5.26, 10.61)	0.62 (0.39, 0.99)	0.0413	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 27 points decrease from baseline) in the Total Score of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.6
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Hepatobiliary Cancer Subscale (HCS)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)			Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)			
OVERALL	335	120 (35.8)	13.37 (6.67, N.A.)	333	170 (51.1)	5.55 (3.68, 7.46)	0.67 (0.53, 0.84)	0.0006	
AGE									0.6907
< 65	162	59 (36.4)	17.77 (6.67, N.A.)	149	70 (47.0)	8.28 (3.75, 10.12)	0.69 (0.49, 0.99)	0.0388	
>= 65	173	61 (35.3)	11.33 (5.55, N.A.)	184	100 (54.3)	3.84 (2.86, 6.24)	0.66 (0.48, 0.91)	0.0098	
SEX									0.5369
MALE	271	98 (36.2)	12.16 (6.47, N.A.)	277	142 (51.3)	5.62 (3.71, 8.25)	0.69 (0.53, 0.90)	0.0048	
FEMALE	64	22 (34.4)	13.37 (5.62, N.A.)	56	28 (50.0)	2.46 (1.45, N.A.)	0.60 (0.34, 1.05)	0.0672	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 10.8 points decrease from baseline) in the Hepatobiliary Cancer Subscale (HCS) of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.6
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Hepatobiliary Cancer Subscale (HCS)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.3889
HBV	99	36 (36.4)	7.13 (3.22, N.A.)	98	46 (46.9)	8.08 (3.71, 10.15)	0.85 (0.55, 1.33)	0.4615	
HCV	27	8 (29.6)	17.77 (3.84, N.A.)	27	16 (59.3)	5.68 (1.87, 13.27)	0.51 (0.22, 1.20)	0.1155	
UNINFECTED	209	76 (36.4)	13.37 (6.47, N.A.)	208	108 (51.9)	3.81 (2.79, 6.54)	0.62 (0.46, 0.84)	0.0016	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.3950
PRESENT	205	69 (33.7)	13.37 (6.67, N.A.)	204	104 (51.0)	3.94 (2.86, 8.25)	0.60 (0.44, 0.82)	0.0010	
ABSENT	130	51 (39.2)	8.57 (4.17, N.A.)	129	66 (51.2)	6.51 (3.48, 13.83)	0.76 (0.52, 1.09)	0.1304	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 10.8 points decrease from baseline) in the Hepatobiliary Cancer Subscale (HCS) of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-ebr2618.sas

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Table 5.6
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Hepatobiliary Cancer Subscale (HCS)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE ALPHA-FETOPROTEIN									0.1135
< 400 NG/ML	225	76 (33.8)	19.94 (8.25, N.A.)	222	122 (55.0)	3.94 (2.79, 6.93)	0.58 (0.44, 0.78)	0.0002	
>= 400 NG/ML	110	44 (40.0)	7.13 (2.86, N.A.)	111	48 (43.2)	6.24 (3.71, 10.61)	0.88 (0.59, 1.34)	0.5546	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 10.8 points decrease from baseline) in the Hepatobiliary Cancer Subscale (HCS) of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.7
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - General (FACT-G)
Total Score
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
OVERALL	335	95 (28.4)	32.16 (14.78, N.A.)	333	130 (39.0)	10.02 (7.33, 13.83)	0.66 (0.51, 0.86)	0.0021	
AGE									0.7103
< 65	162	40 (24.7)	N.A. (32.16, N.A.)	149	48 (32.2)	11.76 (8.87, N.A.)	0.65 (0.43, 0.99)	0.0412	
>= 65	173	55 (31.8)	14.78 (5.72, N.A.)	184	82 (44.6)	7.39 (5.26, 12.55)	0.71 (0.50, 1.00)	0.0522	
SEX									0.7391
MALE	271	73 (26.9)	N.A. (23.52, N.A.)	277	107 (38.6)	10.22 (7.33, 14.98)	0.64 (0.48, 0.87)	0.0034	
FEMALE	64	22 (34.4)	8.11 (5.55, N.A.)	56	23 (41.1)	8.87 (2.27, N.A.)	0.72 (0.40, 1.29)	0.2706	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 16.2 points decrease from baseline) in the Total Score of the FACT-G

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-ebr2618.sas

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Protocol: CA209-9DW

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Table 5.7
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - General (FACT-G)
Total Score
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.6106
HBV	99	22 (22.2)	N.A. (17.28, N.A.)	98	32 (32.7)	14.98 (7.39, N.A.)	0.73 (0.42, 1.26)	0.2476	
HCV	27	6 (22.2)	N.A. (5.85, N.A.)	27	14 (51.9)	5.55 (2.83, N.A.)	0.42 (0.16, 1.09)	0.0659	
UNINFECTED	209	67 (32.1)	23.52 (11.07, N.A.)	208	84 (40.4)	8.87 (6.47, 12.55)	0.65 (0.47, 0.91)	0.0103	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.6331
PRESENT	205	58 (28.3)	N.A. (11.30, N.A.)	204	74 (36.3)	10.61 (5.91, N.A.)	0.70 (0.49, 0.99)	0.0401	
ABSENT	130	37 (28.5)	32.16 (11.07, N.A.)	129	56 (43.4)	8.44 (6.47, N.A.)	0.62 (0.41, 0.94)	0.0232	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 16.2 points decrease from baseline) in the Total Score of the FACT-G

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.7
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - General (FACT-G)
Total Score
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE									0.6358
ALPHA-FETOPROTEIN									
< 400 NG/ML	225	62 (27.6)	32.16 (17.28, N.A.)	222	89 (40.1)	10.22 (6.93, N.A.)	0.69 (0.50, 0.95)	0.0239	
>= 400 NG/ML	110	33 (30.0)	N.A. (10.91, N.A.)	111	41 (36.9)	8.25 (5.26, 14.98)	0.59 (0.37, 0.94)	0.0234	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 16.2 points decrease from baseline) in the Total Score of the FACT-G

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.4
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Emotional Well-Being (EWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)			Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)			
OVERALL	335	108 (32.2)	14.78 (10.91, N.A.)	333	125 (37.5)	11.07 (7.46, 16.56)	0.80 (0.62, 1.04)	0.0975	
AGE									0.4641
< 65	162	52 (32.1)	N.A. (10.91, N.A.)	149	56 (37.6)	10.35 (6.70, N.A.)	0.73 (0.50, 1.06)	0.0987	
>= 65	173	56 (32.4)	11.30 (8.28, N.A.)	184	69 (37.5)	12.06 (5.78, N.A.)	0.88 (0.62, 1.26)	0.5033	
SEX									0.8032
MALE	271	87 (32.1)	14.78 (11.07, N.A.)	277	102 (36.8)	11.07 (7.16, 16.56)	0.81 (0.61, 1.08)	0.1502	
FEMALE	64	21 (32.8)	18.66 (3.88, N.A.)	56	23 (41.1)	15.28 (2.89, N.A.)	0.73 (0.40, 1.33)	0.3156	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 3.6 points decrease from baseline) in the Emotional Well-Being (EWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 5.4
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Emotional Well-Being (EWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.1692
HBV	99	28 (28.3)	N.A. (7.69, N.A.)	98	33 (33.7)	16.56 (8.77, N.A.)	0.92 (0.55, 1.52)	0.7284	
HCV	27	4 (14.8)	N.A. (N.A., N.A.)	27	14 (51.9)	8.25 (2.96, N.A.)	0.30 (0.10, 0.92)	0.0242	
UNINFECTED	209	76 (36.4)	11.33 (9.23, N.A.)	208	78 (37.5)	9.79 (5.52, N.A.)	0.82 (0.60, 1.13)	0.2367	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.3543
PRESENT	205	65 (31.7)	16.95 (10.22, N.A.)	204	77 (37.7)	8.77 (5.55, N.A.)	0.73 (0.52, 1.02)	0.0622	
ABSENT	130	43 (33.1)	14.78 (7.56, N.A.)	129	48 (37.2)	14.06 (7.46, N.A.)	0.91 (0.60, 1.38)	0.6735	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 3.6 points decrease from baseline) in the Emotional Well-Being (EWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.4
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Emotional Well-Being (EWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE									0.7463
ALPHA-FETOPROTEIN									
< 400 NG/ML	225	69 (30.7)	18.66 (11.07, N.A.)	222	85 (38.3)	13.90 (7.46, N.A.)	0.82 (0.60, 1.13)	0.2215	
>= 400 NG/ML	110	39 (35.5)	11.33 (7.13, N.A.)	111	40 (36.0)	7.79 (5.52, 15.28)	0.74 (0.47, 1.15)	0.1781	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 3.6 points decrease from baseline) in the Emotional Well-Being (EWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.5
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Functional Well-Being (FWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)			Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)			
OVERALL	335	150 (44.8)	5.45 (3.78, 9.17)	333	168 (50.5)	5.52 (3.71, 6.37)	0.82 (0.66, 1.03)	0.0813	
AGE									0.9163
< 65	162	72 (44.4)	7.49 (3.75, 23.23)	149	69 (46.3)	5.78 (2.83, 10.02)	0.84 (0.60, 1.17)	0.3004	
>= 65	173	78 (45.1)	3.98 (2.96, 7.39)	184	99 (53.8)	3.91 (2.69, 5.91)	0.82 (0.61, 1.11)	0.2075	
SEX									0.1153
MALE	271	122 (45.0)	5.45 (3.55, 11.04)	277	135 (48.7)	5.65 (3.84, 8.34)	0.89 (0.69, 1.14)	0.3424	
FEMALE	64	28 (43.8)	4.63 (3.25, N.A.)	56	33 (58.9)	2.27 (1.48, 5.59)	0.54 (0.32, 0.91)	0.0181	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Functional Well-Being (FWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.5
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Functional Well-Being (FWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.1046
HBV	99	40 (40.4)	7.49 (2.56, N.A.)	98	48 (49.0)	5.59 (2.79, 9.92)	0.78 (0.51, 1.19)	0.2379	
HCV	27	6 (22.2)	N.A. (12.29, N.A.)	27	15 (55.6)	5.52 (1.41, N.A.)	0.34 (0.13, 0.87)	0.0192	
UNINFECTED	209	104 (49.8)	4.17 (3.25, 5.78)	208	105 (50.5)	4.86 (2.83, 7.39)	0.91 (0.69, 1.20)	0.5133	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.7118
PRESENT	205	88 (42.9)	5.65 (3.55, 12.29)	204	99 (48.5)	4.86 (2.83, 8.25)	0.80 (0.60, 1.07)	0.1294	
ABSENT	130	62 (47.7)	4.63 (3.25, 11.99)	129	69 (53.5)	5.52 (2.79, 8.34)	0.85 (0.61, 1.21)	0.3736	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Functional Well-Being (FWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.5
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Functional Well-Being (FWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE									0.9910
ALPHA-FETOPROTEIN									
< 400 NG/ML	225	96 (42.7)	5.65 (3.78, 16.10)	222	111 (50.0)	5.59 (3.71, 8.34)	0.81 (0.62, 1.07)	0.1436	
>= 400 NG/ML	110	54 (49.1)	4.37 (2.73, 7.49)	111	57 (51.4)	3.84 (2.14, 8.25)	0.82 (0.57, 1.20)	0.3066	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Functional Well-Being (FWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.2
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Physical Well-Being (PWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
OVERALL	335	145 (43.3)	4.70 (3.71, 10.15)	333	191 (57.4)	2.83 (2.14, 4.40)	0.66 (0.53, 0.82)	0.0002	
AGE									0.7571
< 65	162	62 (38.3)	23.26 (5.42, N.A.)	149	72 (48.3)	6.37 (2.17, 8.90)	0.66 (0.47, 0.92)	0.0155	
>= 65	173	83 (48.0)	3.55 (2.23, 4.40)	184	119 (64.7)	2.14 (1.48, 3.48)	0.70 (0.53, 0.93)	0.0138	
SEX									0.3962
MALE	271	115 (42.4)	5.78 (3.71, 20.44)	277	152 (54.9)	2.99 (2.17, 4.67)	0.69 (0.54, 0.87)	0.0024	
FEMALE	64	30 (46.9)	4.14 (2.53, 8.11)	56	39 (69.6)	1.45 (0.85, 2.89)	0.55 (0.34, 0.89)	0.0134	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Physical Well-Being (PWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.2
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Physical Well-Being (PWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.7272
HBV	99	31 (31.3)	27.73 (4.57, N.A.)	98	49 (50.0)	5.29 (2.14, 10.61)	0.59 (0.38, 0.93)	0.0212	
HCV	27	9 (33.3)	N.A. (2.79, N.A.)	27	16 (59.3)	2.96 (1.41, 13.27)	0.50 (0.22, 1.14)	0.0938	
UNINFECTED	209	105 (50.2)	3.75 (2.96, 4.90)	208	126 (60.6)	2.27 (1.91, 3.71)	0.69 (0.53, 0.90)	0.0061	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.3307
PRESENT	205	85 (41.5)	5.42 (3.71, 11.33)	204	107 (52.5)	2.99 (2.17, 7.39)	0.72 (0.54, 0.96)	0.0278	
ABSENT	130	60 (46.2)	4.17 (2.83, 27.73)	129	84 (65.1)	2.14 (1.45, 3.71)	0.59 (0.42, 0.82)	0.0016	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Physical Well-Being (PWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.2
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Physical Well-Being (PWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE									0.5378
ALPHA-FETOPROTEIN									
< 400 NG/ML	225	99 (44.0)	4.14 (3.09, 10.15)	222	132 (59.5)	2.79 (2.10, 4.67)	0.70 (0.54, 0.91)	0.0080	
>= 400 NG/ML	110	46 (41.8)	6.70 (3.98, 23.26)	111	59 (53.2)	2.96 (2.07, 7.39)	0.58 (0.39, 0.86)	0.0060	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Physical Well-Being (PWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Table 5.3
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Social/Family Well-Being (SWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)			Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)			
OVERALL	335	114 (34.0)	14.29 (6.51, N.A.)	333	137 (41.1)	8.25 (5.78, 11.07)	0.79 (0.62, 1.02)	0.0711	
AGE									0.3108
< 65	162	55 (34.0)	28.09 (7.36, N.A.)	149	65 (43.6)	7.29 (3.81, 15.28)	0.71 (0.49, 1.01)	0.0588	
>= 65	173	59 (34.1)	9.30 (5.55, 29.96)	184	72 (39.1)	8.64 (5.22, 16.59)	0.88 (0.62, 1.25)	0.4798	
SEX									0.4209
MALE	271	91 (33.6)	29.96 (6.47, N.A.)	277	116 (41.9)	7.29 (4.86, 10.32)	0.77 (0.59, 1.02)	0.0658	
FEMALE	64	23 (35.9)	9.30 (3.71, 19.32)	56	21 (37.5)	15.28 (2.83, N.A.)	0.95 (0.52, 1.72)	0.8808	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Social/Family Well-Being (SWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-ebr2618.sas

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Table 5.3
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Social/Family Well-Being (SWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
DISEASE ETIOLOGY PER CENTRAL LAB									0.9324
HBV	99	31 (31.3)	14.29 (5.32, N.A.)	98	40 (40.8)	9.46 (4.14, N.A.)	0.78 (0.48, 1.24)	0.2964	
HCV	27	10 (37.0)	7.52 (1.68, N.A.)	27	15 (55.6)	6.01 (1.45, 9.43)	0.74 (0.33, 1.66)	0.4659	
UNINFECTED	209	73 (34.9)	11.30 (6.47, N.A.)	208	82 (39.4)	8.64 (4.86, 16.59)	0.83 (0.60, 1.14)	0.2504	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD									0.6040
PRESENT	205	62 (30.2)	19.32 (9.30, N.A.)	204	77 (37.7)	9.43 (4.86, N.A.)	0.75 (0.54, 1.05)	0.0995	
ABSENT	130	52 (40.0)	7.36 (5.03, N.A.)	129	60 (46.5)	7.29 (4.60, 10.15)	0.85 (0.59, 1.24)	0.4001	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Social/Family Well-Being (SWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-ebr2618.sas

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Table 5.3
Time to First Meaningful Deterioration
Functional Assessment of Cancer Therapy - Hepatobiliary Cancer (FACT-Hep)
Social/Family Well-Being (SWB)
by Significant Subgroups
All Randomized Subjects

	Nivo + Ipi (N = 335)			Sora / Lenva (N = 333)					
	N	Events n (%)	Kaplan Meier median (95% CI) (months)	N	Events n (%)	Kaplan Meier median (95% CI) (months)	Hazard ratio (95% CI) (a)	p-value (b)	Interaction (c)
BASELINE									0.6472
ALPHA-FETOPROTEIN									
< 400 NG/ML	225	78 (34.7)	11.04 (5.78, 29.96)	222	95 (42.8)	7.29 (4.86, 11.07)	0.83 (0.61, 1.12)	0.2271	
>= 400 NG/ML	110	36 (32.7)	N.A. (6.47, N.A.)	111	42 (37.8)	9.00 (4.73, N.A.)	0.73 (0.47, 1.15)	0.1737	

(a) Hazard ratio from unstratified Cox proportional hazard model.

(b) p-value from unstratified log-rank test.

(c) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

First Meaningful Deterioration is defined as a clinically meaningful decline (at least 4.2 points decrease from baseline) in the Social/Family Well-Being (SWB) questionnaire scale of the FACT-Hep

Feb 2024 DBL

Program Path: /pic/projects2/blinded/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ef-ttmdsub-eb2618.sas

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Protocol: CA209-9DW

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Any TEAE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	331 (99.7)	0.48 (0.39, 0.56)	325	323 (99.4)	0.39 (0.30, 0.49)	0.98 (0.84, 1.15) 0.9016	
AGE								0.8733
< 65	162	161 (99.4)	0.44 (0.30, 0.62)	143	141 (98.6)	0.49 (0.30, 0.69)	1.00 (0.80, 1.26) 0.9182	
>= 65	170	170 (100.0)	0.49 (0.36, 0.59)	182	182 (100.0)	0.39 (0.26, 0.49)	0.99 (0.80, 1.22) 0.9599	
SEX								0.7192
MALE	269	269 (100.0)	0.46 (0.36, 0.56)	269	268 (99.6)	0.36 (0.26, 0.49)	1.00 (0.84, 1.18) 0.9499	
FEMALE	63	62 (98.4)	0.56 (0.39, 0.66)	56	55 (98.2)	0.43 (0.33, 0.69)	0.91 (0.63, 1.31) 0.6693	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-sub-eb2618.sas

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Protocol: CA209-9DW

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Any TEAE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5168
HBV	98	97 (99.0)	0.51 (0.30, 0.66)	95	94 (98.9)	0.49 (0.30, 0.69)	0.95 (0.72, 1.27) 0.7966	
HCV	27	27 (100.0)	0.39 (0.16, 0.66)	25	25 (100.0)	0.46 (0.26, 0.72)	1.36 (0.78, 2.37) 0.2751	
UNINFECTED	207	207 (100.0)	0.46 (0.36, 0.59)	205	204 (99.5)	0.36 (0.26, 0.49)	0.99 (0.82, 1.21) 0.9586	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1337
PRESENT	204	203 (99.5)	0.49 (0.39, 0.59)	199	197 (99.0)	0.49 (0.30, 0.62)	1.07 (0.88, 1.31) 0.4289	
ABSENT	128	128 (100.0)	0.46 (0.30, 0.62)	126	126 (100.0)	0.33 (0.26, 0.46)	0.83 (0.65, 1.07) 0.1489	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Any TEAE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.8449
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	224 (100.0)	0.43 (0.30, 0.56)	217	216 (99.5)	0.33 (0.26, 0.46)	0.97 (0.80, 1.17) 0.8098	
>= 400 NG/ML	108	107 (99.1)	0.57 (0.46, 0.66)	108	107 (99.1)	0.53 (0.36, 0.69)	1.00 (0.76, 1.31) 0.9739	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-sub-ebr2618.sas

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Severe TEAE (CTC Grade $\geq$ 3)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	254 (76.5)	2.43 (2.07, 2.92)	325	241 (74.2)	3.98 (3.32, 5.65)	1.11 (0.93, 1.32) 0.2620	
AGE								0.5529
< 65	162	119 (73.5)	2.79 (2.10, 3.68)	143	99 (69.2)	6.51 (3.94, 8.31)	1.20 (0.92, 1.57) 0.1876	
$\geq$ 65	170	135 (79.4)	2.14 (1.58, 2.63)	182	142 (78.0)	3.32 (2.20, 4.17)	1.06 (0.84, 1.34) 0.6388	
SEX								0.4224
MALE	269	205 (76.2)	2.53 (2.10, 3.06)	269	196 (72.9)	4.60 (3.48, 6.31)	1.14 (0.93, 1.39) 0.2001	
FEMALE	63	49 (77.8)	2.07 (1.41, 3.48)	56	45 (80.4)	2.07 (1.38, 4.63)	0.97 (0.64, 1.45) 0.8520	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if $\leq$ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Severe TEAE (CTC Grade $\geq$ 3)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9320
HBV	98	65 (66.3)	3.68 (2.10, 6.74)	95	62 (65.3)	5.49 (3.42, 11.33)	1.06 (0.75, 1.50) 0.7511	
HCV	27	22 (81.5)	2.07 (1.31, 7.59)	25	20 (80.0)	3.71 (1.45, 9.17)	1.03 (0.56, 1.90) 0.9429	
UNINFECTED	207	167 (80.7)	2.20 (1.91, 2.76)	205	159 (77.6)	3.98 (2.66, 5.06)	1.15 (0.93, 1.43) 0.2084	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.6545
PRESENT	204	157 (77.0)	2.33 (2.04, 2.79)	199	154 (77.4)	4.07 (2.96, 6.01)	1.08 (0.86, 1.35) 0.5306	
ABSENT	128	97 (75.8)	2.79 (1.84, 3.98)	126	87 (69.0)	3.98 (2.33, 7.23)	1.16 (0.87, 1.55) 0.3190	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-sub-ebr2618.sas

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Severe TEAE (CTC Grade >= 3)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.1445
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	168 (75.0)	2.76 (2.10, 3.68)	217	161 (74.2)	3.71 (2.56, 5.65)	1.01 (0.81, 1.26) 0.9275	
>= 400 NG/ML	108	86 (79.6)	2.12 (1.54, 2.73)	108	80 (74.1)	4.63 (3.45, 8.34)	1.37 (1.01, 1.86) 0.0464	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-sub-ebr2618.sas

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Serious TEAE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	212 (63.9)	5.16 (3.84, 8.08)	325	175 (53.8)	11.33 (8.74, 14.85)	1.35 (1.11, 1.66) 0.0031	
AGE								0.6575
< 65	162	97 (59.9)	6.05 (3.68, 12.78)	143	70 (49.0)	14.85 (9.43, 20.04)	1.45 (1.07, 1.98) 0.0175	
>= 65	170	115 (67.6)	4.86 (2.56, 8.25)	182	105 (57.7)	9.23 (5.85, 13.73)	1.31 (1.00, 1.71) 0.0461	
SEX								0.9492
MALE	269	169 (62.8)	5.65 (3.78, 9.95)	269	143 (53.2)	11.33 (8.74, 15.77)	1.36 (1.09, 1.71) 0.0064	
FEMALE	63	43 (68.3)	4.27 (2.23, 7.85)	56	32 (57.1)	10.22 (3.42, 22.18)	1.28 (0.81, 2.02) 0.2963	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-sub-eb2618.sas

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Serious TEAE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8263
HBV	98	56 (57.1)	11.99 (2.92, 17.31)	95	44 (46.3)	18.23 (11.33, N.A.)	1.45 (0.98, 2.16) 0.0643	
HCV	27	17 (63.0)	4.53 (2.79, 19.22)	25	14 (56.0)	10.94 (2.92, N.A.)	1.13 (0.55, 2.29) 0.7421	
UNINFECTED	207	139 (67.1)	4.86 (2.92, 6.74)	205	117 (57.1)	9.86 (7.29, 14.29)	1.35 (1.06, 1.73) 0.0167	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4017
PRESENT	204	134 (65.7)	4.34 (2.86, 8.08)	199	118 (59.3)	9.23 (6.87, 12.68)	1.26 (0.98, 1.62) 0.0671	
ABSENT	128	78 (60.9)	6.05 (4.34, 9.95)	126	57 (45.2)	19.15 (9.89, N.A.)	1.56 (1.11, 2.20) 0.0108	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: Serious TEAE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.6112
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	136 (60.7)	7.20 (4.57, 12.88)	217	105 (48.4)	18.23 (10.18, 22.18)	1.41 (1.09, 1.82) 0.0090	
>= 400 NG/ML	108	76 (70.4)	2.86 (2.50, 5.65)	108	70 (64.8)	8.74 (5.49, 10.22)	1.31 (0.94, 1.82) 0.1059	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: TEAE Leading to Treatment Discontinuation

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	112 (33.7)	N.A. (N.A., N.A.)	325	75 (23.1)	N.A. (N.A., N.A.)	1.58 (1.18, 2.12) 0.0020	
AGE								0.5561
< 65	162	46 (28.4)	N.A. (N.A., N.A.)	143	29 (20.3)	N.A. (N.A., N.A.)	1.46 (0.92, 2.33) 0.1057	
>= 65	170	66 (38.8)	N.A. (13.37, N.A.)	182	46 (25.3)	N.A. (N.A., N.A.)	1.72 (1.18, 2.51) 0.0044	
SEX								0.2721
MALE	269	85 (31.6)	N.A. (N.A., N.A.)	269	63 (23.4)	N.A. (N.A., N.A.)	1.45 (1.04, 2.00) 0.0260	
FEMALE	63	27 (42.9)	N.A. (4.96, N.A.)	56	12 (21.4)	N.A. (N.A., N.A.)	2.24 (1.13, 4.43) 0.0171	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: TEAE Leading to Treatment Discontinuation

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6166
HBV	98	20 (20.4)	N.A. (N.A., N.A.)	95	12 (12.6)	N.A. (N.A., N.A.)	1.75 (0.85, 3.57) 0.1231	
HCV	27	12 (44.4)	16.10 (4.73, N.A.)	25	6 (24.0)	N.A. (14.72, N.A.)	2.42 (0.91, 6.46) 0.0701	
UNINFECTED	207	80 (38.6)	N.A. (19.55, N.A.)	205	57 (27.8)	N.A. (N.A., N.A.)	1.46 (1.04, 2.05) 0.0291	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1568
PRESENT	204	73 (35.8)	N.A. (20.34, N.A.)	199	55 (27.6)	N.A. (18.23, N.A.)	1.35 (0.95, 1.91) 0.0968	
ABSENT	128	39 (30.5)	N.A. (N.A., N.A.)	126	20 (15.9)	N.A. (N.A., N.A.)	2.20 (1.28, 3.78) 0.0033	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 7
Time to Event Analyses for Main AE Categories
By Significant Subgroup
All Treated Subjects

Main AE Category: TEAE Leading to Treatment Discontinuation

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.3405
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	80 (35.7)	N.A. (22.18, N.A.)	217	49 (22.6)	N.A. (N.A., N.A.)	1.72 (1.20, 2.46) 0.0025	
>= 400 NG/ML	108	32 (29.6)	N.A. (N.A., N.A.)	108	26 (24.1)	N.A. (17.54, N.A.)	1.34 (0.79, 2.25) 0.2713	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	216 (65.1)	1.25 (0.89, 1.48)	325	180 (55.4)	3.48 (2.76, 5.52)	1.71 (1.40, 2.08) <0.0001	0.0537
AGE								
< 65	162	103 (63.6)	1.25 (0.76, 2.10)	143	85 (59.4)	2.79 (1.64, 3.71)	1.40 (1.05, 1.87) 0.0216	
>= 65	170	113 (66.5)	1.25 (0.85, 1.48)	182	95 (52.2)	4.67 (2.79, 10.41)	2.08 (1.58, 2.75) <0.0001	0.5931
SEX								
MALE	269	174 (64.7)	1.18 (0.82, 1.58)	269	147 (54.6)	3.68 (2.76, 7.66)	1.74 (1.40, 2.18) <0.0001	
FEMALE	63	42 (66.7)	1.41 (0.72, 2.10)	56	33 (58.9)	2.86 (1.38, 4.67)	1.53 (0.97, 2.44) 0.0677	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5228
HBV	98	66 (67.3)	0.85 (0.69, 1.41)	95	53 (55.8)	3.48 (1.48, 9.69)	1.90 (1.31, 2.74) 0.0005	
HCV	27	14 (51.9)	6.24 (0.95, N.A.)	25	15 (60.0)	5.52 (2.27, N.A.)	1.10 (0.52, 2.33) 0.8138	
UNINFECTED	207	136 (65.7)	1.41 (0.85, 1.77)	205	112 (54.6)	3.42 (2.33, 5.45)	1.71 (1.32, 2.19) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9961
PRESENT	204	127 (62.3)	1.41 (0.95, 1.91)	199	106 (53.3)	3.68 (2.79, 7.33)	1.76 (1.36, 2.28) <0.0001	
ABSENT	128	89 (69.5)	0.95 (0.76, 1.41)	126	74 (58.7)	3.35 (1.68, 9.40)	1.67 (1.22, 2.28) 0.0013	
BASELINE ALPHA-- FETOPROTEIN								0.3939
< 400 NG/ML	224	152 (67.9)	0.99 (0.76, 1.48)	217	120 (55.3)	3.71 (2.40, 7.66)	1.78 (1.40, 2.27) <0.0001	
>= 400 NG/ML	108	64 (59.3)	1.41 (0.79, 2.86)	108	60 (55.6)	3.02 (1.64, 10.12)	1.56 (1.09, 2.22) 0.0141	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	116 (34.9)	23.95 (9.63, N.A.)	325	23 (7.1)	N.A.	6.86 (4.38, 10.75) <0.0001	0.3318
AGE								
< 65	162	58 (35.8)	23.95 (7.75, N.A.)	143	12 (8.4)	N.A.	5.50 (2.95, 10.26) <0.0001	
>= 65	170	58 (34.1)	19.78 (5.19, N.A.)	182	11 (6.0)	N.A.	8.48 (4.44, 16.20) <0.0001	0.6977
SEX								
MALE	269	89 (33.1)	23.95 (9.63, N.A.)	269	19 (7.1)	N.A.	6.64 (4.04, 10.91) <0.0001	
FEMALE	63	27 (42.9)	19.78 (1.41, N.A.)	56	4 (7.1)	N.A.	7.82 (2.73, 22.38) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2767
HBV	98	37 (37.8)	N.A. (2.40, N.A.)	95	4 (4.2)	N.A.	12.29 (4.37, 34.60) <0.0001	
HCV	27	2 (7.4)	N.A. (18.10, N.A.)	25	1 (4.0)	N.A.	1.78 (0.16, 20.45) 0.6371	
UNINFECTED	207	77 (37.2)	16.85 (6.01, N.A.)	205	18 (8.8)	N.A.	5.87 (3.51, 9.83) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Pruritus

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5431
PRESENT	204	69 (33.8)	23.95 (5.78, N.A.)	199	15 (7.5)	N.A.	6.24 (3.56, 10.92) <0.0001	
ABSENT	128	47 (36.7)	19.78 (7.39, N.A.)	126	8 (6.3)	N.A.	8.03 (3.79, 17.03) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.7966
< 400 NG/ML	224	76 (33.9)	N.A. (14.29, N.A.)	217	14 (6.5)	N.A.	7.08 (4.00, 12.53) <0.0001	
>= 400 NG/ML	108	40 (37.0)	16.85 (4.80, N.A.)	108	9 (8.3)	N.A.	6.63 (3.21, 13.72) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	82 (24.7)	N.A.	325	33 (10.2)	N.A.	3.24 (2.14, 4.91) <0.0001	0.1224
AGE								
< 65	162	38 (23.5)	N.A.	143	18 (12.6)	N.A.	2.33 (1.31, 4.13) 0.0030	
>= 65	170	44 (25.9)	N.A. (18.37, N.A.)	182	15 (8.2)	N.A. (28.06, N.A.)	4.49 (2.46, 8.21) <0.0001	0.4590
SEX								
MALE	269	70 (26.0)	N.A.	269	27 (10.0)	N.A.	3.40 (2.17, 5.34) <0.0001	0.0749
FEMALE	63	12 (19.0)	N.A.	56	6 (10.7)	N.A. (24.80, N.A.)	2.50 (0.88, 7.12) 0.0749	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5482
HBV	98	24 (24.5)	N.A. (18.37, N.A.)	95	9 (9.5)	N.A. (24.80, N.A.)	3.67 (1.64, 8.19) 0.0007	
HCV	27	7 (25.9)	N.A. (6.24, N.A.)	25	1 (4.0)	N.A.	8.89 (1.09, 72.68) 0.0140	
UNINFECTED	207	51 (24.6)	N.A.	205	23 (11.2)	N.A. (28.06, N.A.)	2.82 (1.71, 4.65) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0898
PRESENT	204	44 (21.6)	N.A.	199	23 (11.6)	N.A.	2.46 (1.47, 4.10) 0.0004	
ABSENT	128	38 (29.7)	N.A. (18.37, N.A.)	126	10 (7.9)	N.A. (28.06, N.A.)	5.19 (2.51, 10.76) <0.0001	0.6881
BASELINE ALPHA-- FETOPROTEIN								
< 400 NG/ML	224	58 (25.9)	N.A.	217	22 (10.1)	N.A.	3.33 (2.02, 5.49) <0.0001	
>= 400 NG/ML	108	24 (22.2)	N.A.	108	11 (10.2)	N.A. (24.80, N.A.)	3.00 (1.43, 6.30) 0.0022	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	19 (5.7)	N.A.	325	4 (1.2)	N.A.	5.25 (1.78, 15.43) 0.0008	0.1650
AGE								
< 65	162	8 (4.9)	N.A.	143	3 (2.1)	N.A.	2.53 (0.67, 9.53) 0.1563	
>= 65	170	11 (6.5)	N.A.	182	1 (0.5)	N.A.	13.94 (1.80, >99.99) 0.0009	0.9904
SEX								
MALE	269	10 (3.7)	N.A.	269	4 (1.5)	N.A.	2.75 (0.86, 8.79) 0.0744	
FEMALE	63	9 (14.3)	N.A.	56	0	N.E.	N.E. 0.0023	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9999
HBV	98	5 (5.1)	N.A.	95	0	N.E.	N.E. 0.0237	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E. 0.3070	
UNINFECTED	207	13 (6.3)	N.A.	205	4 (2.0)	N.A.	3.61 (1.18, 11.10) 0.0163	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Rash Maculo-Papular

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9466
PRESENT	204	10 (4.9)	N.A.	199	2 (1.0)	N.A.	5.60 (1.23, 25.58) 0.0122	
ABSENT	128	9 (7.0)	N.A.	126	2 (1.6)	N.A.	4.86 (1.05, 22.49) 0.0255	
BASELINE ALPHA-- FETOPROTEIN								0.1004
< 400 NG/ML	224	14 (6.3)	N.A.	217	1 (0.5)	N.A.	15.09 (1.98, >99.99) 0.0005	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	3 (2.8)	N.A.	1.96 (0.47, 8.20) 0.3498	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	10 (3.1)	N.A.	1.23 (0.52, 2.90) 0.6357	0.7508
AGE								
< 65	162	6 (3.7)	N.A.	143	4 (2.8)	N.A.	1.43 (0.40, 5.06) 0.5801	
>= 65	170	5 (2.9)	N.A.	182	6 (3.3)	N.A.	1.09 (0.33, 3.57) 0.8887	0.8539
SEX								
MALE	269	10 (3.7)	N.A.	269	9 (3.3)	N.A.	1.28 (0.52, 3.16) 0.5860	
FEMALE	63	1 (1.6)	N.A.	56	1 (1.8)	N.A.	0.96 (0.06, 15.28) 0.9746	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9866
HBV	98	1 (1.0)	N.A.	95	1 (1.1)	N.A.	1.13 (0.07, 18.11) 0.9333	
HCV	27	0	N.E.	25	1 (4.0)	N.A.	N.E. 0.3743	
UNINFECTED	207	10 (4.8)	N.A.	205	8 (3.9)	N.A.	1.39 (0.55, 3.52) 0.4882	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Dry Skin

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4850
PRESENT	204	5 (2.5)	N.A.	199	6 (3.0)	N.A.	0.93 (0.28, 3.06) 0.9094	
ABSENT	128	6 (4.7)	N.A.	126	4 (3.2)	N.A.	1.68 (0.47, 5.96) 0.4169	
BASELINE ALPHA-- FETOPROTEIN								0.9877
< 400 NG/ML	224	5 (2.2)	N.A.	217	10 (4.6)	N.A.	0.55 (0.19, 1.61) 0.2681	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	0	N.E.	N.E. 0.0099	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Palmar-Plantar Erythrodysesthesia Syndrome

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	N.A.	325	105 (32.3)	N.A.	0.09 (0.04, 0.16) <0.0001	0.5379
AGE								
< 65	162	6 (3.7)	N.A.	143	45 (31.5)	N.A.	0.11 (0.05, 0.25) <0.0001	
>= 65	170	4 (2.4)	N.A.	182	60 (33.0)	N.A. (11.93, N.A.)	0.07 (0.02, 0.18) <0.0001	0.9015
SEX								
MALE	269	8 (3.0)	N.A.	269	84 (31.2)	N.A.	0.09 (0.04, 0.18) <0.0001	0.9015
FEMALE	63	2 (3.2)	N.A.	56	21 (37.5)	11.93 (4.37, N.A.)	0.08 (0.02, 0.34) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Palmar-Plantar Erythrodysesthesia Syndrome

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1329
HBV	98	5 (5.1)	N.A.	95	38 (40.0)	11.04 (3.71, N.A.)	0.11 (0.04, 0.29) <0.0001	
HCV	27	2 (7.4)	N.A.	25	7 (28.0)	N.A. (5.52, N.A.)	0.32 (0.07, 1.54) 0.1345	
UNINFECTED	207	3 (1.4)	N.A.	205	60 (29.3)	N.A.	0.04 (0.01, 0.14) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Palmar-Plantar Erythrodysesthesia Syndrome

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7914
PRESENT	204	6 (2.9)	N.A.	199	58 (29.1)	N.A.	0.09 (0.04, 0.22) <0.0001	
ABSENT	128	4 (3.1)	N.A.	126	47 (37.3)	N.A. (8.94, N.A.)	0.08 (0.03, 0.21) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.1490
< 400 NG/ML	224	9 (4.0)	N.A.	217	69 (31.8)	N.A.	0.12 (0.06, 0.23) <0.0001	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	36 (33.3)	N.A.	0.03 (<0.01, 0.20) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	5 (1.5)	N.A.	325	19 (5.8)	N.A.	0.30 (0.11, 0.80) 0.0104	0.6638
AGE < 65	162	3 (1.9)	N.A.	143	12 (8.4)	N.A.	0.24 (0.07, 0.83) 0.0147	
>= 65	170	2 (1.2)	N.A.	182	7 (3.8)	N.A.	0.39 (0.08, 1.89) 0.2271	
SEX								0.8789
MALE	269	2 (0.7)	N.A.	269	9 (3.3)	N.A.	0.26 (0.06, 1.20) 0.0619	
FEMALE	63	3 (4.8)	N.A.	56	10 (17.9)	N.A. (13.80, N.A.)	0.30 (0.08, 1.10) 0.0537	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9217
HBV	98	2 (2.0)	N.A.	95	8 (8.4)	N.A.	0.29 (0.06, 1.37) 0.0955	
HCV	27	1 (3.7)	N.A. (13.17, N.A.)	25	0	N.E.	N.E. 0.2636	
UNINFECTED	207	2 (1.0)	N.A.	205	11 (5.4)	N.A.	0.21 (0.05, 0.93) 0.0229	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Alopecia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3665
PRESENT	204	3 (1.5)	N.A.	199	7 (3.5)	N.A.	0.48 (0.12, 1.86) 0.2776	
ABSENT	128	2 (1.6)	N.A.	126	12 (9.5)	N.A.	0.19 (0.04, 0.85) 0.0149	
BASELINE ALPHA-- FETOPROTEIN								0.9888
< 400 NG/ML	224	5 (2.2)	N.A.	217	12 (5.5)	N.A.	0.48 (0.17, 1.35) 0.1539	
>= 400 NG/ML	108	0	N.E.	108	7 (6.5)	N.A.	N.E. 0.0173	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	200 (60.2)	2.92 (2.20, 3.91)	325	241 (74.2)	1.64 (1.28, 2.20)	0.68 (0.56, 0.82) <0.0001	0.9861
AGE								
< 65	162	103 (63.6)	2.92 (2.07, 3.94)	143	107 (74.8)	1.77 (1.05, 2.69)	0.68 (0.52, 0.90) 0.0060	
>= 65	170	97 (57.1)	2.76 (2.10, 5.65)	182	134 (73.6)	1.64 (1.22, 2.73)	0.68 (0.52, 0.88) 0.0034	0.3517
SEX								
MALE	269	160 (59.5)	3.09 (2.20, 4.63)	269	199 (74.0)	1.54 (1.18, 2.14)	0.65 (0.53, 0.80) <0.0001	
FEMALE	63	40 (63.5)	2.23 (1.18, 3.94)	56	42 (75.0)	2.10 (1.25, 3.58)	0.82 (0.53, 1.27) 0.3751	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1621
HBV	98	61 (62.2)	2.40 (1.87, 5.59)	95	66 (69.5)	2.69 (1.51, 3.71)	0.83 (0.59, 1.18) 0.3128	
HCV	27	13 (48.1)	4.63 (1.51, N.A.)	25	21 (84.0)	0.92 (0.49, 2.92)	0.42 (0.21, 0.85) 0.0133	
UNINFECTED	207	126 (60.9)	2.76 (2.17, 3.94)	205	154 (75.1)	1.41 (1.05, 2.14)	0.66 (0.52, 0.84) 0.0005	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4572
PRESENT	204	121 (59.3)	2.86 (2.10, 3.91)	199	144 (72.4)	2.00 (1.38, 2.69)	0.72 (0.56, 0.91) 0.0068	
ABSENT	128	79 (61.7)	3.09 (2.10, 6.08)	126	97 (77.0)	1.25 (0.79, 2.69)	0.63 (0.47, 0.85) 0.0023	
BASELINE ALPHA-- FETOPROTEIN								0.8093
< 400 NG/ML	224	142 (63.4)	2.76 (2.10, 3.75)	217	162 (74.7)	1.41 (1.18, 2.14)	0.69 (0.55, 0.86) 0.0012	
>= 400 NG/ML	108	58 (53.7)	3.65 (2.17, 6.34)	108	79 (73.1)	2.10 (1.15, 3.09)	0.67 (0.47, 0.94) 0.0189	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	77 (23.2)	N.A.	325	133 (40.9)	11.24 (8.94, 15.41)	0.56 (0.42, 0.74) <0.0001	0.5165
AGE < 65	162	36 (22.2)	N.A.	143	58 (40.6)	12.02 (6.44, 20.76)	0.50 (0.33, 0.76) 0.0009	
>= 65	170	41 (24.1)	N.A.	182	75 (41.2)	11.24 (8.51, 15.61)	0.63 (0.43, 0.92) 0.0154	
SEX								0.0261*
MALE	269	56 (20.8)	N.A.	269	113 (42.0)	11.04 (8.51, 14.65)	0.47 (0.34, 0.65) <0.0001	
FEMALE	63	21 (33.3)	22.77 (5.13, N.A.)	56	20 (35.7)	15.41 (6.41, N.A.)	1.04 (0.56, 1.93) 0.8880	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0231*
HBV	98	10 (10.2)	N.A.	95	35 (36.8)	15.61 (6.41, N.A.)	0.26 (0.13, 0.53) <0.0001	
HCV	27	4 (14.8)	N.A.	25	12 (48.0)	11.24 (5.59, N.A.)	0.29 (0.09, 0.93) 0.0275	
UNINFECTED	207	63 (30.4)	N.A. (12.29, N.A.)	205	86 (42.0)	10.97 (8.21, 14.06)	0.73 (0.53, 1.01) 0.0586	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1011
PRESENT	204	39 (19.1)	N.A.	199	81 (40.7)	11.04 (6.87, 14.06)	0.44 (0.30, 0.65) <0.0001	
ABSENT	128	38 (29.7)	N.A. (12.29, N.A.)	126	52 (41.3)	14.65 (8.21, N.A.)	0.73 (0.48, 1.12) 0.1485	
BASELINE ALPHA-- FETOPROTEIN								0.1644
< 400 NG/ML	224	62 (27.7)	N.A. (21.52, N.A.)	217	95 (43.8)	11.04 (8.51, 14.06)	0.62 (0.45, 0.85) 0.0032	
>= 400 NG/ML	108	15 (13.9)	N.A.	108	38 (35.2)	15.41 (6.80, N.A.)	0.40 (0.22, 0.74) 0.0023	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Nausea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	34 (10.2)	N.A.	325	54 (16.6)	N.A.	0.66 (0.43, 1.01) 0.0559	0.3141
AGE								
< 65	162	17 (10.5)	N.A.	143	18 (12.6)	N.A.	0.87 (0.45, 1.70) 0.6908	
>= 65	170	17 (10.0)	N.A.	182	36 (19.8)	N.A.	0.55 (0.31, 0.99) 0.0417	0.6288
SEX								
MALE	269	23 (8.6)	N.A.	269	41 (15.2)	N.A.	0.61 (0.37, 1.02) 0.0576	
FEMALE	63	11 (17.5)	N.A.	56	13 (23.2)	N.A. (12.48, N.A.)	0.77 (0.35, 1.73) 0.5318	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Nausea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4900
HBV	98	5 (5.1)	N.A.	95	12 (12.6)	N.A.	0.43 (0.15, 1.23) 0.1042	
HCV	27	2 (7.4)	N.A.	25	6 (24.0)	N.A. (10.51, N.A.)	0.44 (0.09, 2.20) 0.3079	
UNINFECTED	207	27 (13.0)	N.A.	205	36 (17.6)	N.A.	0.78 (0.47, 1.29) 0.3350	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Nausea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8257
PRESENT	204	20 (9.8)	N.A.	199	30 (15.1)	N.A.	0.68 (0.39, 1.20) 0.1802	
ABSENT	128	14 (10.9)	N.A.	126	24 (19.0)	N.A.	0.64 (0.33, 1.23) 0.1745	
BASELINE ALPHA-- FETOPROTEIN								0.6158
< 400 NG/ML	224	27 (12.1)	N.A.	217	40 (18.4)	N.A.	0.71 (0.44, 1.16) 0.1657	
>= 400 NG/ML	108	7 (6.5)	N.A.	108	14 (13.0)	N.A.	0.50 (0.20, 1.25) 0.1290	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Constipation

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	33 (9.9)	N.A.	325	52 (16.0)	N.A.	0.65 (0.42, 1.00) 0.0509	0.5338
AGE < 65	162	16 (9.9)	N.A.	143	25 (17.5)	N.A.	0.54 (0.29, 1.02) 0.0550	
>= 65	170	17 (10.0)	N.A.	182	27 (14.8)	(19.15, N.A.) N.A.	0.77 (0.42, 1.41) 0.3878	
SEX								0.7037
MALE	269	28 (10.4)	N.A.	269	44 (16.4)	N.A.	0.68 (0.42, 1.09) 0.1105	
FEMALE	63	5 (7.9)	N.A.	56	8 (14.3)	N.A.	0.52 (0.17, 1.60) 0.2453	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Constipation

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1269
HBV	98	11 (11.2)	N.A.	95	8 (8.4)	N.A.	1.47 (0.59, 3.67) 0.4021	
HCV	27	3 (11.1)	N.A.	25	5 (20.0)	18.66 (N.A., N.A.)	0.57 (0.13, 2.55) 0.4588	
UNINFECTED	207	19 (9.2)	N.A.	205	39 (19.0)	N.A.	0.48 (0.28, 0.84) 0.0083	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Constipation

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9934
PRESENT	204	17 (8.3)	N.A.	199	27 (13.6)	N.A.	0.65 (0.35, 1.20) 0.1662	
ABSENT	128	16 (12.5)	N.A.	126	25 (19.8)	N.A.	0.64 (0.34, 1.21) 0.1684	
BASELINE ALPHA-- FETOPROTEIN								0.0653
< 400 NG/ML	224	26 (11.6)	N.A.	217	31 (14.3)	N.A.	0.88 (0.52, 1.48) 0.6176	
>= 400 NG/ML	108	7 (6.5)	N.A.	108	21 (19.4)	N.A. (19.15, N.A.)	0.30 (0.13, 0.72) 0.0044	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Ascites

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	32 (9.6)	N.A.	325	31 (9.5)	N.A.	1.12 (0.68, 1.84) 0.6657	0.1623
AGE								
< 65	162	17 (10.5)	N.A.	143	9 (6.3)	N.A.	1.83 (0.81, 4.11) 0.1386	
>= 65	170	15 (8.8)	N.A.	182	22 (12.1)	N.A.	0.82 (0.42, 1.60) 0.5604	0.5580
SEX								
MALE	269	27 (10.0)	N.A.	269	25 (9.3)	N.A.	1.18 (0.68, 2.04) 0.5557	
FEMALE	63	5 (7.9)	N.A.	56	6 (10.7)	N.A.	0.86 (0.26, 2.83) 0.8064	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Ascites

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6500
HBV	98	10 (10.2)	N.A.	95	7 (7.4)	N.A.	1.68 (0.64, 4.42) 0.2877	
HCV	27	3 (11.1)	N.A.	25	3 (12.0)	N.A. (13.90, N.A.)	1.25 (0.25, 6.21) 0.7862	
UNINFECTED	207	19 (9.2)	N.A.	205	21 (10.2)	N.A.	0.92 (0.49, 1.73) 0.8021	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Ascites

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2732
PRESENT	204	22 (10.8)	N.A.	199	17 (8.5)	N.A.	1.45 (0.77, 2.73) 0.2521	
ABSENT	128	10 (7.8)	N.A.	126	14 (11.1)	N.A.	0.74 (0.33, 1.68) 0.4678	
BASELINE ALPHA-- FETOPROTEIN								0.8384
< 400 NG/ML	224	19 (8.5)	N.A.	217	18 (8.3)	N.A.	1.11 (0.58, 2.12) 0.7624	
>= 400 NG/ML	108	13 (12.0)	N.A.	108	13 (12.0)	N.A.	1.11 (0.51, 2.42) 0.7839	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva		Test for Interaction P-value (4)(5)
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)		
OVERALL	332	27 (8.1)	N.A.	325	56 (17.2)	34.76 (34.76, N.A.)	0.49 (0.31, 0.78) 0.0021		
AGE									0.8922
< 65	162	16 (9.9)	N.A.	143	30 (21.0)	34.76 (22.51, N.A.)	0.47 (0.25, 0.87) 0.0136		
>= 65	170	11 (6.5)	N.A.	182	26 (14.3)	N.A.	0.49 (0.24, 0.99) 0.0422		
SEX									0.0281*
MALE	269	19 (7.1)	N.A.	269	51 (19.0)	34.76 (34.76, N.A.)	0.40 (0.23, 0.67) 0.0004		
FEMALE	63	8 (12.7)	N.A. (19.15, N.A.)	56	5 (8.9)	N.A. (22.51, N.A.)	1.44 (0.47, 4.44) 0.5195		

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1974
HBV	98	11 (11.2)	N.A.	95	13 (13.7)	N.A. (22.51, N.A.)	0.88 (0.39, 1.97) 0.7467	
HCV	27	1 (3.7)	N.A.	25	5 (20.0)	N.A. (11.30, N.A.)	0.22 (0.03, 1.86) 0.1259	
UNINFECTED	207	15 (7.2)	N.A.	205	38 (18.5)	34.76 (34.76, N.A.)	0.40 (0.22, 0.72) 0.0019	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2593
PRESENT	204	20 (9.8)	N.A.	199	34 (17.1)	34.76 (22.51, N.A.)	0.59 (0.34, 1.03) 0.0603	
ABSENT	128	7 (5.5)	N.A.	126	22 (17.5)	N.A.	0.33 (0.14, 0.78) 0.0078	
BASELINE ALPHA-- FETOPROTEIN								0.4951
< 400 NG/ML	224	14 (6.3)	N.A.	217	34 (15.7)	N.A.	0.42 (0.23, 0.79) 0.0055	
>= 400 NG/ML	108	13 (12.0)	N.A.	108	22 (20.4)	34.76 (22.51, N.A.)	0.60 (0.30, 1.21) 0.1497	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Vomiting

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	26 (7.8)	24.77 (N.A., N.A.)	325	36 (11.1)	N.A.	0.83 (0.50, 1.38) 0.4677	0.3359
AGE < 65	162	12 (7.4)	N.A.	143	10 (7.0)	N.A.	1.15 (0.49, 2.65) 0.7509	
>= 65	170	14 (8.2)	24.77 (N.A., N.A.)	182	26 (14.3)	N.A.	0.72 (0.37, 1.38) 0.3212	
SEX								0.5343
MALE	269	17 (6.3)	24.77 (N.A., N.A.)	269	27 (10.0)	N.A.	0.75 (0.41, 1.40) 0.3680	
FEMALE	63	9 (14.3)	N.A.	56	9 (16.1)	N.A.	0.93 (0.37, 2.36) 0.8899	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Vomiting

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0149*
HBV	98	9 (9.2)	N.A.	95	1 (1.1)	N.A.	9.57 (1.21, 75.64) 0.0087	
HCV	27	1 (3.7)	N.A.	25	6 (24.0)	N.A. (13.93, N.A.)	0.20 (0.02, 1.66) 0.0976	
UNINFECTED	207	16 (7.7)	24.77 (N.A., N.A.)	205	29 (14.1)	N.A.	0.62 (0.33, 1.15) 0.1235	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Vomiting

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8082
PRESENT	204	16 (7.8)	N.A.	199	21 (10.6)	N.A.	0.86 (0.44, 1.66) 0.6497	
ABSENT	128	10 (7.8)	24.77 (N.A., N.A.)	126	15 (11.9)	N.A.	0.78 (0.35, 1.74) 0.5380	
BASELINE ALPHA-- FETOPROTEIN								0.1798
< 400 NG/ML	224	21 (9.4)	24.77 (N.A., N.A.)	217	23 (10.6)	N.A.	1.06 (0.58, 1.93) 0.8584	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	13 (12.0)	N.A.	0.43 (0.15, 1.22) 0.1035	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Pain Upper

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	21 (6.3)	N.A.	325	33 (10.2)	N.A.	0.65 (0.38, 1.13) 0.1270	0.7170
AGE								
< 65	162	15 (9.3)	N.A.	143	20 (14.0)	N.A.	0.67 (0.34, 1.32) 0.2428	
>= 65	170	6 (3.5)	N.A.	182	13 (7.1)	N.A.	0.53 (0.20, 1.42) 0.1997	0.1608
SEX								
MALE	269	14 (5.2)	N.A.	269	28 (10.4)	N.A.	0.54 (0.28, 1.02) 0.0552	0.1608
FEMALE	63	7 (11.1)	N.A. (23.00, N.A.)	56	5 (8.9)	N.A.	1.25 (0.39, 3.99) 0.7030	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Pain Upper

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3654
HBV	98	7 (7.1)	N.A.	95	6 (6.3)	N.A.	1.21 (0.41, 3.61) 0.7273	
HCV	27	2 (7.4)	N.A.	25	3 (12.0)	N.A.	0.86 (0.14, 5.20) 0.8738	
UNINFECTED	207	12 (5.8)	N.A.	205	24 (11.7)	N.A.	0.49 (0.24, 0.99) 0.0421	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Pain Upper

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5774
PRESENT	204	15 (7.4)	N.A.	199	21 (10.6)	N.A.	0.75 (0.38, 1.45) 0.3874	
ABSENT	128	6 (4.7)	N.A.	126	12 (9.5)	N.A.	0.50 (0.19, 1.34) 0.1586	
BASELINE ALPHA-- FETOPROTEIN								0.8865
< 400 NG/ML	224	15 (6.7)	N.A.	217	24 (11.1)	N.A.	0.63 (0.33, 1.19) 0.1519	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	9 (8.3)	N.A.	0.77 (0.27, 2.16) 0.6131	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Colitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	16 (4.8)	N.A.	325	0	N.E.	N.E. <0.0001	
AGE								N.M.E.
< 65	162	8 (4.9)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	8 (4.7)	N.M.E.	182	0	N.E.	N.E.	
SEX								>0.9999
MALE	269	12 (4.5)	N.A.	269	0	N.E.	N.E. 0.0002	
FEMALE	63	4 (6.3)	N.A.	56	0	N.E.	N.E. 0.0453	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Colitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	1 (1.0)	N.A.	95	0	N.E.	N.E. 0.2956	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E. 0.2835	
UNINFECTED	207	14 (6.8)	N.A.	205	0	N.E.	N.E. <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Colitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								>0.9999
PRESENT	204	10 (4.9)	N.A.	199	0	N.E.	N.E. 0.0009	
ABSENT	128	6 (4.7)	N.A.	126	0	N.E.	N.E. 0.0078	
BASELINE ALPHA-- FETOPROTEIN								>0.9999
< 400 NG/ML	224	12 (5.4)	N.A.	217	0	N.E.	N.E. 0.0002	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	0	N.E.	N.E. 0.0457	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Dry Mouth

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	14 (4.2)	N.A.	325	12 (3.7)	N.A.	1.32 (0.61, 2.86) 0.4766	0.6285
AGE								
< 65	162	7 (4.3)	N.A.	143	4 (2.8)	N.A.	1.63 (0.48, 5.58) 0.4323	
>= 65	170	7 (4.1)	N.A.	182	8 (4.4)	N.A.	1.18 (0.43, 3.25) 0.7520	0.2575
SEX								
MALE	269	10 (3.7)	N.A.	269	11 (4.1)	N.A.	1.04 (0.44, 2.45) 0.9290	
FEMALE	63	4 (6.3)	N.A.	56	1 (1.8)	N.A.	4.20 (0.47, 37.62) 0.1628	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Dry Mouth

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9998
HBV	98	4 (4.1)	N.A.	95	0	N.E.	N.E. 0.0329	
HCV	27	0	N.E.	25	1 (4.0)	N.A.	N.E. 0.3954	
UNINFECTED	207	10 (4.8)	N.A.	205	11 (5.4)	N.A.	0.99 (0.42, 2.34) 0.9882	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Dry Mouth

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7239
PRESENT	204	8 (3.9)	N.A.	199	6 (3.0)	N.A.	1.55 (0.54, 4.49) 0.4117	
ABSENT	128	6 (4.7)	N.A.	126	6 (4.8)	N.A.	1.10 (0.36, 3.43) 0.8634	
BASELINE ALPHA-- FETOPROTEIN								0.4939
< 400 NG/ML	224	12 (5.4)	N.A.	217	9 (4.1)	N.A.	1.51 (0.64, 3.59) 0.3447	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	3 (2.8)	N.A.	0.61 (0.10, 3.73) 0.5912	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Distension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	24 (7.4)	N.A.	0.53 (0.27, 1.05) 0.0632	0.9062
AGE								
< 65	162	6 (3.7)	N.A.	143	9 (6.3)	N.A.	0.55 (0.19, 1.55) 0.2470	
>= 65	170	7 (4.1)	N.A.	182	15 (8.2)	N.A.	0.54 (0.22, 1.33) 0.1752	0.7812
SEX								
MALE	269	10 (3.7)	N.A.	269	18 (6.7)	N.A.	0.57 (0.26, 1.24) 0.1508	
FEMALE	63	3 (4.8)	N.A.	56	6 (10.7)	N.A.	0.41 (0.10, 1.69) 0.2049	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Distension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8051
HBV	98	5 (5.1)	N.A.	95	9 (9.5)	N.A.	0.59 (0.20, 1.77) 0.3438	
HCV	27	1 (3.7)	N.A. (17.28, N.A.)	25	4 (16.0)	N.A. (11.96, N.A.)	0.20 (0.02, 1.84) 0.1181	
UNINFECTED	207	7 (3.4)	N.A.	205	11 (5.4)	N.A.	0.64 (0.25, 1.67) 0.3577	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Abdominal Distension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0261*
PRESENT	204	5 (2.5)	N.A.	199	18 (9.0)	N.A.	0.29 (0.11, 0.77) 0.0084	
ABSENT	128	8 (6.3)	N.A.	126	6 (4.8)	N.A.	1.24 (0.42, 3.59) 0.6973	
BASELINE ALPHA-- FETOPROTEIN								0.8097
< 400 NG/ML	224	9 (4.0)	N.A.	217	16 (7.4)	N.A.	0.54 (0.24, 1.23) 0.1352	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	8 (7.4)	N.A.	0.56 (0.17, 1.87) 0.3412	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Dyspepsia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	N.A.	325	20 (6.2)	N.A.	0.57 (0.27, 1.21) 0.1388	0.5003
AGE								
< 65	162	4 (2.5)	N.A.	143	9 (6.3)	N.A.	0.43 (0.13, 1.41) 0.1525	
>= 65	170	6 (3.5)	N.A.	182	11 (6.0)	N.A.	0.72 (0.27, 1.94) 0.5133	0.3306
SEX								
MALE	269	6 (2.2)	N.A.	269	16 (5.9)	N.A.	0.44 (0.17, 1.13) 0.0791	
FEMALE	63	4 (6.3)	N.A.	56	4 (7.1)	N.A.	0.96 (0.24, 3.84) 0.9554	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Dyspepsia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9639
HBV	98	4 (4.1)	N.A.	95	7 (7.4)	N.A.	0.67 (0.20, 2.30) 0.5254	
HCV	27	0	N.E.	25	5 (20.0)	N.A.	N.E. 0.0517	
UNINFECTED	207	6 (2.9)	N.A.	205	8 (3.9)	N.A.	0.81 (0.28, 2.35) 0.7020	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Dyspepsia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8113
PRESENT	204	7 (3.4)	N.A.	199	13 (6.5)	N.A.	0.63 (0.25, 1.57) 0.3138	
ABSENT	128	3 (2.3)	N.A.	126	7 (5.6)	N.A.	0.47 (0.12, 1.83) 0.2679	
BASELINE ALPHA-- FETOPROTEIN								0.9850
< 400 NG/ML	224	6 (2.7)	N.A.	217	12 (5.5)	N.A.	0.56 (0.21, 1.48) 0.2350	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	8 (7.4)	N.A.	0.62 (0.19, 2.05) 0.4253	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Stomatitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	7 (2.1)	N.A.	325	29 (8.9)	N.A.	0.26 (0.11, 0.60) 0.0006	0.0502
AGE < 65	162	1 (0.6)	N.A.	143	15 (10.5)	N.A.	0.06 (<0.01, 0.0002)	
>= 65	170	6 (3.5)	N.A.	182	14 (7.7)	N.A.	0.55 (0.21, 0.2208)	
SEX								0.4638
MALE	269	6 (2.2)	N.A.	269	22 (8.2)	N.A.	0.31 (0.13, 0.0069)	
FEMALE	63	1 (1.6)	N.A.	56	7 (12.5)	N.A.	0.13 (0.02, 0.0232)	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Stomatitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5903
HBV	98	1 (1.0)	N.A.	95	9 (9.5)	N.A.	0.12 (0.02, 0.94) 0.0156	
HCV	27	0	N.E.	25	3 (12.0)	N.A.	N.E. 0.1090	
UNINFECTED	207	6 (2.9)	N.A.	205	17 (8.3)	N.A.	0.38 (0.15, 0.96) 0.0340	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Stomatitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0800
PRESENT	204	5 (2.5)	N.A.	199	10 (5.0)	N.A.	0.55 (0.19, 1.62) 0.2711	
ABSENT	128	2 (1.6)	N.A.	126	19 (15.1)	N.A.	0.11 (0.03, 0.47) 0.0003	
BASELINE ALPHA-- FETOPROTEIN								0.6090
< 400 NG/ML	224	6 (2.7)	N.A.	217	22 (10.1)	N.A.	0.29 (0.12, 0.72) 0.0042	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	7 (6.5)	N.A.	0.16 (0.02, 1.31) 0.0511	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Gastroesophageal Reflux Disease

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	6 (1.8)	N.A. (23.98, N.A.)	325	10 (3.1)	N.A.	0.71 (0.26, 1.96) 0.5034	0.5930
AGE < 65	162	3 (1.9)	N.A.	143	3 (2.1)	N.A.	0.99 (0.20, 4.92) 0.9908	
>= 65	170	3 (1.8)	N.A. (23.98, N.A.)	182	7 (3.8)	N.A.	0.59 (0.15, 2.29) 0.4383	
SEX								0.8026
MALE	269	5 (1.9)	N.A.	269	9 (3.3)	N.A.	0.65 (0.22, 1.94) 0.4344	
FEMALE	63	1 (1.6)	N.A. (23.98, N.A.)	56	1 (1.8)	N.A.	1.13 (0.07, 18.27) 0.9304	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Gastroesophageal Reflux Disease

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	2 (2.0)	N.M.E.	95	6 (6.3)	N.M.E.	N.M.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	3 (1.4)	N.M.E.	205	4 (2.0)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Gastroesophageal Reflux Disease

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2443
PRESENT	204	4 (2.0)	N.A.	199	9 (4.5)	N.A.	0.50 (0.15, 1.63) 0.2407	
ABSENT	128	2 (1.6)	N.A. (23.98, N.A.)	126	1 (0.8)	N.A.	3.57 (0.30, 42.93) 0.2896	N.M.E.
BASELINE ALPHA-- FETOPROTEIN								
< 400 NG/ML	224	3 (1.3)	N.M.E.	217	6 (2.8)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	3 (2.8)	N.M.E.	108	4 (3.7)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Haemorrhoids

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	2 (0.6)	N.A.	325	11 (3.4)	N.A.	0.20 (0.05, 0.92) 0.0216	
AGE								N.M.E.
< 65	162	0	N.E.	143	4 (2.8)	N.M.E.	N.E.	
>= 65	170	2 (1.2)	N.M.E.	182	7 (3.8)	N.M.E.	N.M.E.	
SEX								0.9996
MALE	269	2 (0.7)	N.A.	269	11 (4.1)	N.A.	0.21 (0.05, 0.94) 0.0244	
FEMALE	63	0	N.E.	56	0	N.E.	N.E. N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Haemorrhoids

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	4 (4.2)	N.M.E.	N.E.	
HCV	27	0	N.E.	25	1 (4.0)	N.M.E.	N.E.	
UNINFECTED	207	2 (1.0)	N.M.E.	205	6 (2.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Haemorrhoids

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	1 (0.5)	N.M.E.	199	6 (3.0)	N.M.E.	N.M.E.	
ABSENT	128	1 (0.8)	N.M.E.	126	5 (4.0)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								N.M.E.
< 400 NG/ML	224	2 (0.9)	N.M.E.	217	7 (3.2)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	0	N.E.	108	4 (3.7)	N.M.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	191 (57.5)	2.10 (1.91, 2.83)	325	174 (53.5)	5.49 (3.75, 8.21)	1.32 (1.07, 1.62) 0.0095	0.1416
AGE								
< 65	162	106 (65.4)	2.07 (1.45, 3.06)	143	75 (52.4)	6.44 (3.68, 8.90)	1.52 (1.13, 2.05) 0.0055	
>= 65	170	85 (50.0)	2.50 (1.87, 3.52)	182	99 (54.4)	4.60 (3.38, 8.34)	1.13 (0.84, 1.51) 0.4290	0.8305
SEX								
MALE	269	153 (56.9)	2.10 (1.94, 2.83)	269	144 (53.5)	5.45 (3.71, 8.31)	1.30 (1.04, 1.64) 0.0237	
FEMALE	63	38 (60.3)	2.50 (1.38, 5.91)	56	30 (53.6)	5.49 (2.79, 10.12)	1.36 (0.84, 2.20) 0.2163	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6576
HBV	98	57 (58.2)	2.07 (1.58, 3.88)	95	53 (55.8)	4.60 (2.86, 10.02)	1.35 (0.93, 1.97) 0.1190	
HCV	27	22 (81.5)	0.72 (0.69, 1.94)	25	20 (80.0)	6.44 (1.41, 8.31)	1.78 (0.96, 3.30) 0.0636	
UNINFECTED	207	112 (54.1)	2.53 (1.94, 3.94)	205	101 (49.3)	6.70 (3.78, 10.22)	1.29 (0.98, 1.69) 0.0696	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.6823
PRESENT	204	118 (57.8)	2.07 (1.71, 2.79)	199	106 (53.3)	6.01 (3.65, 8.31)	1.40 (1.08, 1.83) 0.0122	
ABSENT	128	73 (57.0)	2.53 (1.45, 8.80)	126	68 (54.0)	5.49 (3.38, 10.22)	1.21 (0.87, 1.69) 0.2579	
BASELINE ALPHA-- FETOPROTEIN								0.4362
< 400 NG/ML	224	137 (61.2)	2.10 (1.71, 2.83)	217	117 (53.9)	5.49 (3.68, 8.87)	1.39 (1.08, 1.78) 0.0095	
>= 400 NG/ML	108	54 (50.0)	2.14 (1.41, 4.17)	108	57 (52.8)	4.67 (2.92, 9.17)	1.20 (0.82, 1.74) 0.3541	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	99 (29.8)	N.A.	325	47 (14.5)	N.A.	2.53 (1.79, 3.58) <0.0001	0.7286
AGE								
< 65	162	58 (35.8)	N.A.	143	23 (16.1)	N.A.	2.65 (1.64, 4.31) <0.0001	
>= 65	170	41 (24.1)	(10.55, N.A.) N.A.	182	24 (13.2)	N.A.	2.31 (1.39, 3.83) 0.0009	0.8717
SEX								
MALE	269	81 (30.1)	N.A.	269	39 (14.5)	N.A.	2.55 (1.74, 3.74) <0.0001	
FEMALE	63	18 (28.6)	N.A. (13.37, N.A.)	56	8 (14.3)	N.A.	2.42 (1.05, 5.57) 0.0326	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1866
HBV	98	28 (28.6)	N.A. (13.37, N.A.)	95	16 (16.8)	N.A.	2.08 (1.12, 3.85) 0.0179	
HCV	27	18 (66.7)	1.40 (0.69, 17.18)	25	5 (20.0)	N.A. (10.22, N.A.)	5.88 (2.15, 16.08) 0.0001	
UNINFECTED	207	53 (25.6)	N.A.	205	26 (12.7)	N.A.	2.39 (1.49, 3.83) 0.0002	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2046
PRESENT	204	68 (33.3)	N.A. (8.28, N.A.)	199	28 (14.1)	N.A.	3.05 (1.96, 4.75) <0.0001	
ABSENT	128	31 (24.2)	N.A.	126	19 (15.1)	N.A.	1.83 (1.03, 3.24) 0.0366	
BASELINE ALPHA-- FETOPROTEIN								0.8474
< 400 NG/ML	224	64 (28.6)	N.A.	217	30 (13.8)	N.A.	2.48 (1.61, 3.83) <0.0001	
>= 400 NG/ML	108	35 (32.4)	N.A. (3.65, N.A.)	108	17 (15.7)	N.A.	2.75 (1.54, 4.92) 0.0004	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Alanine Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	82 (24.7)	N.A.	325	36 (11.1)	N.A.	2.68 (1.81, 3.96) <0.0001	0.9173
AGE								
< 65	162	48 (29.6)	N.A.	143	19 (13.3)	N.A.	2.59 (1.52, 4.41) 0.0003	
>= 65	170	34 (20.0)	N.A.	182	17 (9.3)	N.A.	2.63 (1.47, 4.72) 0.0008	0.9314
SEX								
MALE	269	65 (24.2)	N.A.	269	29 (10.8)	N.A.	2.64 (1.70, 4.10) <0.0001	
FEMALE	63	17 (27.0)	N.A.	56	7 (12.5)	N.A.	2.78 (1.15, 6.71) 0.0186	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Alanine Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4975
HBV	98	19 (19.4)	N.A.	95	10 (10.5)	N.A.	2.22 (1.03, 4.80) 0.0365	
HCV	27	15 (55.6)	2.04 (0.69, N.A.)	25	5 (20.0)	N.A. (10.22, N.A.)	4.38 (1.58, 12.17) 0.0023	
UNINFECTED	207	48 (23.2)	N.A.	205	21 (10.2)	N.A.	2.61 (1.56, 4.37) 0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Alanine Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.6383
PRESENT	204	54 (26.5)	N.A.	199	22 (11.1)	N.A.	2.94 (1.79, 4.83) <0.0001	
ABSENT	128	28 (21.9)	N.A.	126	14 (11.1)	N.A.	2.31 (1.22, 4.40) 0.0085	
BASELINE ALPHA-- FETOPROTEIN								0.9980
< 400 NG/ML	224	52 (23.2)	N.A.	217	22 (10.1)	N.A.	2.67 (1.62, 4.41) <0.0001	
>= 400 NG/ML	108	30 (27.8)	N.A.	108	14 (13.0)	N.A.	2.88 (1.52, 5.45) 0.0007	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Lipase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	61 (18.4)	N.A.	325	25 (7.7)	N.A.	2.94 (1.84, 4.69) <0.0001	0.9581
AGE								
< 65	162	31 (19.1)	N.A.	143	11 (7.7)	N.A.	2.91 (1.46, 5.81) 0.0015	
>= 65	170	30 (17.6)	N.A.	182	14 (7.7)	N.A.	2.94 (1.56, 5.56) 0.0005	0.9440
SEX								
MALE	269	50 (18.6)	N.A.	269	21 (7.8)	N.A.	2.99 (1.79, 4.98) <0.0001	
FEMALE	63	11 (17.5)	N.A.	56	4 (7.1)	N.A. (21.19, N.A.)	2.71 (0.86, 8.55) 0.0765	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Lipase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3996
HBV	98	15 (15.3)	N.A.	95	6 (6.3)	N.A.	3.07 (1.19, 7.93) 0.0147	
HCV	27	4 (14.8)	N.A. (10.94, N.A.)	25	4 (16.0)	N.A.	1.21 (0.30, 4.86) 0.7867	
UNINFECTED	207	42 (20.3)	N.A.	205	15 (7.3)	N.A.	3.38 (1.87, 6.11) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Lipase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1956
PRESENT	204	34 (16.7)	N.A.	199	10 (5.0)	N.A.	4.14 (2.04, 8.39) <0.0001	
ABSENT	128	27 (21.1)	N.A.	126	15 (11.9)	N.A.	2.15 (1.14, 4.05) 0.0150	
BASELINE ALPHA-- FETOPROTEIN								0.4632
< 400 NG/ML	224	44 (19.6)	N.A.	217	16 (7.4)	N.A.	3.37 (1.90, 5.97) <0.0001	
>= 400 NG/ML	108	17 (15.7)	N.A.	108	9 (8.3)	N.A. (21.19, N.A.)	2.21 (0.98, 5.00) 0.0504	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Amylase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	51 (15.4)	N.A.	325	13 (4.0)	N.A.	4.78 (2.60, 8.80) <0.0001	0.3334
AGE								
< 65	162	31 (19.1)	N.A.	143	5 (3.5)	N.A.	6.50 (2.53, 16.73) <0.0001	
>= 65	170	20 (11.8)	N.A.	182	8 (4.4)	N.A.	3.54 (1.56, 8.04) 0.0013	0.9864
SEX								
MALE	269	42 (15.6)	N.A.	269	13 (4.8)	N.A.	4.06 (2.18, 7.57) <0.0001	
FEMALE	63	9 (14.3)	N.A.	56	0	N.E.	N.E. 0.0022	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Amylase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9144
HBV	98	13 (13.3)	N.A.	95	4 (4.2)	N.A.	4.02 (1.31, 12.37) 0.0086	
HCV	27	3 (11.1)	N.A.	25	1 (4.0)	N.A. (12.48, N.A.)	3.76 (0.39, 36.23) 0.2187	
UNINFECTED	207	35 (16.9)	N.A.	205	8 (3.9)	N.A.	5.23 (2.43, 11.29) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Amylase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8906
PRESENT	204	29 (14.2)	N.A.	199	7 (3.5)	N.A.	4.92 (2.15, 11.24) <0.0001	
ABSENT	128	22 (17.2)	N.A.	126	6 (4.8)	N.A.	4.59 (1.86, 11.32) 0.0003	
BASELINE ALPHA-- FETOPROTEIN								0.8638
< 400 NG/ML	224	38 (17.0)	N.A.	217	10 (4.6)	N.A.	4.64 (2.31, 9.33) <0.0001	
>= 400 NG/ML	108	13 (12.0)	N.A.	108	3 (2.8)	N.A.	5.15 (1.46, 18.19) 0.0046	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Bilirubin Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	44 (13.3)	N.A. (24.31, N.A.)	325	35 (10.8)	N.A.	1.43 (0.91, 2.23) 0.1167	0.4191
AGE < 65	162	26 (16.0)	N.A. (24.31, N.A.)	143	15 (10.5)	N.A.	1.71 (0.90, 3.24) 0.0949	
>= 65	170	18 (10.6)	N.A.	182	20 (11.0)	N.A.	1.13 (0.60, 2.14) 0.7086	
SEX								0.8075
MALE	269	35 (13.0)	N.A. (24.31, N.A.)	269	28 (10.4)	N.A.	1.46 (0.89, 2.41) 0.1346	
FEMALE	63	9 (14.3)	N.A.	56	7 (12.5)	N.A. (16.03, N.A.)	1.27 (0.47, 3.41) 0.6344	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Bilirubin Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2213
HBV	98	13 (13.3)	24.31 (N.A., N.A.)	95	11 (11.6)	N.A.	1.41 (0.63, 3.18) 0.4032	
HCV	27	8 (29.6)	N.A. (2.79, N.A.)	25	2 (8.0)	N.A.	4.98 (1.05, 23.51) 0.0246	
UNINFECTED	207	23 (11.1)	N.A.	205	22 (10.7)	N.A.	1.12 (0.62, 2.02) 0.6993	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Bilirubin Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1479
PRESENT	204	21 (10.3)	N.A.	199	22 (11.1)	N.A.	1.06 (0.58, 1.93) 0.8472	
ABSENT	128	23 (18.0)	24.31 (24.31, N.A.)	126	13 (10.3)	N.A.	2.06 (1.04, 4.09) 0.0352	
BASELINE ALPHA-- FETOPROTEIN								0.2860
< 400 NG/ML	224	30 (13.4)	24.31 (24.31, N.A.)	217	20 (9.2)	N.A.	1.74 (0.98, 3.08) 0.0547	
>= 400 NG/ML	108	14 (13.0)	N.A.	108	15 (13.9)	N.A.	1.05 (0.50, 2.17) 0.9064	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Weight Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	31 (9.3)	26.68 (N.A., N.A.)	325	67 (20.6)	N.A.	0.49 (0.32, 0.75) 0.0008	0.4558
AGE < 65	162	18 (11.1)	N.A.	143	29 (20.3)	N.A. (18.79, N.A.)	0.55 (0.31, 1.00) 0.0466	
>= 65	170	13 (7.6)	26.68 (N.A., N.A.)	182	38 (20.9)	N.A.	0.42 (0.22, 0.79) 0.0059	
SEX								0.3535
MALE	269	22 (8.2)	26.68 (N.A., N.A.)	269	55 (20.4)	N.A.	0.43 (0.26, 0.71) 0.0007	
FEMALE	63	9 (14.3)	N.A.	56	12 (21.4)	N.A. (8.21, N.A.)	0.68 (0.29, 1.61) 0.3790	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Weight Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0203*
HBV	98	12 (12.2)	N.A.	95	11 (11.6)	N.A.	1.34 (0.59, 3.04) 0.4837	
HCV	27	2 (7.4)	N.A.	25	8 (32.0)	N.A. (6.47, N.A.)	0.30 (0.06, 1.41) 0.1054	
UNINFECTED	207	17 (8.2)	26.68 (N.A., N.A.)	205	48 (23.4)	N.A. (18.79, N.A.)	0.34 (0.20, 0.60) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Weight Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8009
PRESENT	204	20 (9.8)	N.A.	199	44 (22.1)	N.A.	0.47 (0.27, 0.79) 0.0039	
ABSENT	128	11 (8.6)	26.68 (N.A., N.A.)	126	23 (18.3)	N.A.	0.53 (0.26, 1.09) 0.0790	
BASELINE ALPHA-- FETOPROTEIN								0.1084
< 400 NG/ML	224	27 (12.1)	26.68 (N.A., N.A.)	217	48 (22.1)	N.A.	0.60 (0.37, 0.96) 0.0299	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	19 (17.6)	N.A. (14.69, N.A.)	0.21 (0.07, 0.63) 0.0023	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Platelet Count Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	27 (8.1)	N.A.	325	28 (8.6)	N.A.	1.04 (0.61, 1.77) 0.8810	0.9145
AGE								
< 65	162	15 (9.3)	N.A.	143	13 (9.1)	N.A.	1.04 (0.49, 2.19) 0.9222	
>= 65	170	12 (7.1)	N.A.	182	15 (8.2)	N.A.	1.00 (0.47, 2.14) 0.9952	0.5990
SEX								
MALE	269	23 (8.6)	N.A.	269	23 (8.6)	N.A.	1.10 (0.62, 1.97) 0.7394	
FEMALE	63	4 (6.3)	N.A.	56	5 (8.9)	N.A.	0.75 (0.20, 2.79) 0.6644	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Platelet Count Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9803
HBV	98	6 (6.1)	N.A.	95	7 (7.4)	N.A.	0.95 (0.32, 2.81) 0.9191	
HCV	27	4 (14.8)	N.A. (9.43, N.A.)	25	4 (16.0)	N.A.	1.05 (0.26, 4.23) 0.9407	
UNINFECTED	207	17 (8.2)	N.A.	205	17 (8.3)	N.A.	1.09 (0.55, 2.14) 0.8063	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Platelet Count Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7807
PRESENT	204	15 (7.4)	N.A.	199	14 (7.0)	N.A.	1.09 (0.53, 2.26) 0.8163	
ABSENT	128	12 (9.4)	N.A.	126	14 (11.1)	N.A.	0.98 (0.45, 2.12) 0.9537	
BASELINE ALPHA-- FETOPROTEIN								0.5386
< 400 NG/ML	224	22 (9.8)	N.A.	217	21 (9.7)	N.A.	1.13 (0.62, 2.06) 0.6817	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	7 (6.5)	N.A.	0.77 (0.24, 2.45) 0.6567	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	15 (4.5)	N.A.	325	11 (3.4)	N.A.	1.47 (0.67, 3.21) 0.3321	0.5766
AGE < 65	162	8 (4.9)	N.A.	143	4 (2.8)	N.A.	1.88 (0.57, 6.26) 0.2946	
>= 65	170	7 (4.1)	N.A.	182	7 (3.8)	N.A.	1.22 (0.42, 3.50) 0.7144	
SEX								0.2728
MALE	269	12 (4.5)	N.A.	269	7 (2.6)	N.A.	1.90 (0.75, 4.85) 0.1705	
FEMALE	63	3 (4.8)	N.A.	56	4 (7.1)	N.A.	0.70 (0.16, 3.15) 0.6419	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7182
HBV	98	3 (3.1)	N.A.	95	1 (1.1)	N.A.	3.65 (0.38, 35.09) 0.2300	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	12 (5.8)	N.A.	205	10 (4.9)	N.A.	1.24 (0.53, 2.89) 0.6166	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Alkaline Phosphatase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2629
PRESENT	204	9 (4.4)	N.A.	199	4 (2.0)	N.A.	2.49 (0.76, 8.08) 0.1172	
ABSENT	128	6 (4.7)	N.A.	126	7 (5.6)	N.A.	0.93 (0.31, 2.77) 0.8905	
BASELINE ALPHA-- FETOPROTEIN								0.0717
< 400 NG/ML	224	13 (5.8)	N.A.	217	6 (2.8)	N.A.	2.39 (0.91, 6.30) 0.0693	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	5 (4.6)	N.A.	0.41 (0.08, 2.19) 0.2859	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Creatinine Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	15 (4.5)	26.68 (N.A., N.A.)	325	15 (4.6)	43.47 (N.A., N.A.)	1.24 (0.59, 2.61) 0.5624	0.6273
AGE < 65	162	5 (3.1)	N.A.	143	5 (3.5)	N.A.	0.91 (0.26, 3.16) 0.8789	
>= 65	170	10 (5.9)	26.68 (N.A., N.A.)	182	10 (5.5)	43.47 (N.A., N.A.)	1.56 (0.62, 3.90) 0.3400	
SEX								0.4788
MALE	269	11 (4.1)	26.68 (N.A., N.A.)	269	13 (4.8)	43.47 (N.A., N.A.)	1.08 (0.47, 2.50) 0.8483	
FEMALE	63	4 (6.3)	N.A.	56	2 (3.6)	N.A.	2.00 (0.37, 10.91) 0.4142	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Creatinine Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3977
HBV	98	2 (2.0)	N.A.	95	3 (3.2)	N.A.	0.75 (0.12, 4.50) 0.7510	
HCV	27	1 (3.7)	N.A. (19.22, N.A.)	25	3 (12.0)	N.A.	0.27 (0.03, 2.69) 0.2328	
UNINFECTED	207	12 (5.8)	26.68 (N.A., N.A.)	205	9 (4.4)	43.47 (N.A., N.A.)	1.81 (0.72, 4.54) 0.2015	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Creatinine Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8088
PRESENT	204	8 (3.9)	N.A.	199	8 (4.0)	N.A.	1.11 (0.41, 2.95) 0.8401	
ABSENT	128	7 (5.5)	26.68 (N.A., N.A.)	126	7 (5.6)	43.47 (N.A., N.A.)	1.44 (0.47, 4.42) 0.5205	
BASELINE ALPHA-- FETOPROTEIN								0.9500
< 400 NG/ML	224	13 (5.8)	26.68 (N.A., N.A.)	217	13 (6.0)	43.47 (N.A., N.A.)	1.27 (0.57, 2.81) 0.5628	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	2 (1.9)	N.A.	1.19 (0.17, 8.48) 0.8619	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Magnesium Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	0	N.E.	N.E. 0.0007	N.M.E. 0.9998
AGE								
< 65	162	3 (1.9)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	8 (4.7)	N.M.E.	182	0	N.E.	N.E.	
SEX								
MALE	269	10 (3.7)	N.A.	269	0	N.E.	N.E. 0.0010	0.9998
FEMALE	63	1 (1.6)	N.A.	56	0	N.E.	N.E. 0.3231	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Magnesium Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	1 (1.0)	N.M.E.	95	0	N.E.	N.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	9 (4.3)	N.M.E.	205	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Magnesium Decreased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	3 (1.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	8 (6.3)	N.M.E.	126	0	N.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								N.M.E.
< 400 NG/ML	224	9 (4.0)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	2 (1.9)	N.M.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	8 (2.4)	N.A.	325	13 (4.0)	N.A.	0.67 (0.28, 1.63) 0.3785	0.2064
AGE < 65	162	6 (3.7)	N.A.	143	5 (3.5)	N.A.	1.12 (0.34, 3.70) 0.8514	
>= 65	170	2 (1.2)	N.A.	182	8 (4.4)	N.A.	0.32 (0.07, 1.51) 0.1279	
SEX								0.3541
MALE	269	6 (2.2)	N.A.	269	12 (4.5)	N.A.	0.55 (0.21, 1.49) 0.2344	
FEMALE	63	2 (3.2)	N.A.	56	1 (1.8)	N.A.	2.02 (0.18, 22.35) 0.5566	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3928
HBV	98	1 (1.0)	N.A.	95	6 (6.3)	N.A.	0.19 (0.02, 1.58) 0.0859	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E. 0.3070	
UNINFECTED	207	6 (2.9)	N.A.	205	7 (3.4)	N.A.	0.90 (0.30, 2.72) 0.8579	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Blood Thyroid Stimulating Hormone Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.6621
PRESENT	204	3 (1.5)	N.A.	199	6 (3.0)	N.A.	0.57 (0.14, 2.27) 0.4164	
ABSENT	128	5 (3.9)	N.A.	126	7 (5.6)	N.A.	0.79 (0.25, 2.49) 0.6823	
BASELINE ALPHA-- FETOPROTEIN								0.3564
< 400 NG/ML	224	7 (3.1)	N.A.	217	9 (4.1)	N.A.	0.84 (0.31, 2.28) 0.7384	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	4 (3.7)	N.A.	0.30 (0.03, 2.72) 0.2581	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	181 (54.5)	3.52 (2.53, 5.16)	325	186 (57.2)	4.34 (3.22, 7.29)	0.98 (0.80, 1.21) 0.8855	0.8613
AGE								
< 65	162	83 (51.2)	5.16 (2.76, 10.15)	143	72 (50.3)	6.37 (3.45, 18.20)	1.02 (0.75, 1.40) 0.8827	
>= 65	170	98 (57.6)	2.76 (1.58, 3.71)	182	114 (62.6)	3.42 (1.41, 5.78)	0.99 (0.75, 1.29) 0.9217	0.5726
SEX								
MALE	269	151 (56.1)	3.35 (2.10, 5.95)	269	154 (57.2)	4.44 (2.10, 7.29)	1.01 (0.80, 1.26) 0.9373	
FEMALE	63	30 (47.6)	3.52 (1.94, N.A.)	56	32 (57.1)	3.75 (1.41, 11.47)	0.90 (0.54, 1.47) 0.6668	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3406
HBV	98	42 (42.9)	6.83 (3.55, N.A.)	95	42 (44.2)	9.63 (4.73, N.A.)	1.00 (0.65, 1.53) 0.9907	
HCV	27	14 (51.9)	2.99 (0.59, N.A.)	25	11 (44.0)	15.44 (3.25, N.A.)	1.69 (0.76, 3.76) 0.1914	
UNINFECTED	207	125 (60.4)	2.53 (1.71, 3.61)	205	133 (64.9)	2.23 (1.41, 3.84)	0.92 (0.72, 1.18) 0.5302	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0527
PRESENT	204	114 (55.9)	3.19 (1.97, 5.16)	199	105 (52.8)	5.55 (3.42, 9.10)	1.17 (0.90, 1.53) 0.2396	
ABSENT	128	67 (52.3)	3.75 (2.33, 11.83)	126	81 (64.3)	3.25 (1.35, 7.00)	0.75 (0.54, 1.04) 0.0877	
BASELINE ALPHA-- FETOPROTEIN								0.0506
< 400 NG/ML	224	120 (53.6)	3.52 (2.20, 6.37)	217	134 (61.8)	3.25 (1.41, 5.55)	0.85 (0.66, 1.09) 0.2037	
>= 400 NG/ML	108	61 (56.5)	3.25 (1.94, 6.41)	108	52 (48.1)	8.08 (3.75, 11.96)	1.33 (0.92, 1.93) 0.1289	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	66 (19.9)	N.A.	325	68 (20.9)	N.A.	1.03 (0.73, 1.44) 0.8686	0.5667
AGE								
< 65	162	26 (16.0)	N.A.	143	26 (18.2)	N.A.	0.94 (0.54, 1.62) 0.8203	
>= 65	170	40 (23.5)	N.A.	182	42 (23.1)	N.A. (21.16, N.A.)	1.13 (0.73, 1.74) 0.5869	0.5079
SEX								
MALE	269	56 (20.8)	N.A.	269	56 (20.8)	N.A.	1.08 (0.74, 1.57) 0.6825	
FEMALE	63	10 (15.9)	N.A.	56	12 (21.4)	N.A.	0.81 (0.35, 1.88) 0.6296	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1993
HBV	98	9 (9.2)	N.A.	95	5 (5.3)	N.A.	1.92 (0.64, 5.72) 0.2358	
HCV	27	7 (25.9)	N.A. (2.99, N.A.)	25	4 (16.0)	N.A. (12.25, N.A.)	2.15 (0.63, 7.39) 0.2119	
UNINFECTED	207	50 (24.2)	N.A.	205	59 (28.8)	N.A. (21.16, N.A.)	0.88 (0.60, 1.28) 0.4910	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Asthenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5329
PRESENT	204	44 (21.6)	N.A.	199	42 (21.1)	N.A.	1.13 (0.74, 1.73) 0.5630	
ABSENT	128	22 (17.2)	N.A.	126	26 (20.6)	N.A. (21.16, N.A.)	0.87 (0.49, 1.54) 0.6315	
BASELINE ALPHA-- FETOPROTEIN								0.1940
< 400 NG/ML	224	43 (19.2)	N.A.	217	50 (23.0)	N.A.	0.88 (0.58, 1.32) 0.5249	
>= 400 NG/ML	108	23 (21.3)	N.A.	108	18 (16.7)	N.A.	1.47 (0.79, 2.73) 0.2178	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	52 (15.7)	N.A.	325	32 (9.8)	N.A.	1.83 (1.17, 2.86) 0.0071	0.7656
AGE								
< 65	162	28 (17.3)	N.A.	143	16 (11.2)	N.A.	1.74 (0.93, 3.27) 0.0813	
>= 65	170	24 (14.1)	N.A.	182	16 (8.8)	N.A.	1.88 (1.00, 3.54) 0.0480	0.3314
SEX								
MALE	269	44 (16.4)	N.A.	269	25 (9.3)	N.A.	1.96 (1.20, 3.21) 0.0065	
FEMALE	63	8 (12.7)	N.A.	56	7 (12.5)	N.A. (24.80, N.A.)	1.35 (0.47, 3.89) 0.5802	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3103
HBV	98	12 (12.2)	N.A.	95	12 (12.6)	N.A. (24.80, N.A.)	1.15 (0.50, 2.61) 0.7455	
HCV	27	4 (14.8)	N.A. (19.22, N.A.)	25	3 (12.0)	17.64 (13.93, N.A.)	1.08 (0.23, 5.13) 0.9269	
UNINFECTED	207	36 (17.4)	N.A.	205	17 (8.3)	N.A.	2.42 (1.35, 4.31) 0.0020	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8372
PRESENT	204	34 (16.7)	N.A.	199	20 (10.1)	N.A.	1.97 (1.12, 3.47) 0.0160	
ABSENT	128	18 (14.1)	N.A.	126	12 (9.5)	N.A.	1.60 (0.77, 3.33) 0.2074	
BASELINE ALPHA-- FETOPROTEIN								0.6759
< 400 NG/ML	224	33 (14.7)	N.A.	217	19 (8.8)	N.A.	1.91 (1.09, 3.37) 0.0224	
>= 400 NG/ML	108	19 (17.6)	N.A.	108	13 (12.0)	N.A. (13.93, N.A.)	1.56 (0.75, 3.25) 0.2339	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	49 (14.8)	N.A.	325	64 (19.7)	N.A.	0.80 (0.55, 1.16) 0.2298	0.6424
AGE								
< 65	162	28 (17.3)	N.A.	143	29 (20.3)	N.A.	0.87 (0.52, 1.46) 0.5954	
>= 65	170	21 (12.4)	N.A.	182	35 (19.2)	N.A.	0.71 (0.41, 1.22) 0.2110	0.4690
SEX								
MALE	269	37 (13.8)	N.A.	269	53 (19.7)	N.A.	0.75 (0.49, 1.14) 0.1729	
FEMALE	63	12 (19.0)	N.A. (18.33, N.A.)	56	11 (19.6)	N.A. (18.20, N.A.)	0.98 (0.43, 2.23) 0.9603	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4290
HBV	98	13 (13.3)	N.A.	95	18 (18.9)	N.A.	0.73 (0.36, 1.50) 0.3970	
HCV	27	4 (14.8)	N.A.	25	2 (8.0)	N.A.	2.25 (0.41, 12.34) 0.3360	
UNINFECTED	207	32 (15.5)	N.A.	205	44 (21.5)	N.A.	0.74 (0.47, 1.17) 0.1939	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Fatigue

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8509
PRESENT	204	26 (12.7)	N.A.	199	33 (16.6)	N.A.	0.83 (0.50, 1.39) 0.4812	
ABSENT	128	23 (18.0)	N.A.	126	31 (24.6)	N.A.	0.76 (0.44, 1.30) 0.3165	
BASELINE ALPHA-- FETOPROTEIN								0.1633
< 400 NG/ML	224	41 (18.3)	N.A.	217	46 (21.2)	N.A.	0.92 (0.60, 1.40) 0.7037	
>= 400 NG/ML	108	8 (7.4)	N.A.	108	18 (16.7)	N.A.	0.46 (0.20, 1.06) 0.0614	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	42 (12.7)	N.A.	325	41 (12.6)	N.A.	1.16 (0.75, 1.79) 0.4948	0.4574
AGE								
< 65	162	16 (9.9)	N.A.	143	10 (7.0)	N.A.	1.55 (0.70, 3.43) 0.2728	
>= 65	170	26 (15.3)	N.A.	182	31 (17.0)	N.A.	1.10 (0.65, 1.86) 0.7182	0.7695
SEX								
MALE	269	34 (12.6)	N.A.	269	33 (12.3)	N.A.	1.20 (0.74, 1.95) 0.4488	
FEMALE	63	8 (12.7)	N.A.	56	8 (14.3)	N.A. (19.71, N.A.)	1.00 (0.37, 2.67) 0.9995	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5763
HBV	98	9 (9.2)	N.A.	95	6 (6.3)	N.A.	1.76 (0.63, 4.95) 0.2784	
HCV	27	3 (11.1)	N.A.	25	2 (8.0)	N.A.	1.76 (0.29, 10.53) 0.5324	
UNINFECTED	207	30 (14.5)	N.A.	205	33 (16.1)	N.A.	1.00 (0.61, 1.65) 0.9949	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Oedema Peripheral

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4096
PRESENT	204	27 (13.2)	N.A.	199	23 (11.6)	N.A.	1.33 (0.76, 2.33) 0.3092	
ABSENT	128	15 (11.7)	N.A.	126	18 (14.3)	N.A.	0.94 (0.48, 1.88) 0.8715	
BASELINE ALPHA-- FETOPROTEIN								0.6826
< 400 NG/ML	224	30 (13.4)	N.A.	217	31 (14.3)	N.A.	1.09 (0.66, 1.81) 0.7294	
>= 400 NG/ML	108	12 (11.1)	N.A.	108	10 (9.3)	N.A.	1.36 (0.58, 3.18) 0.4738	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	9 (2.7)	N.A.	325	13 (4.0)	N.A.	0.73 (0.31, 1.71) 0.4679	0.9361
AGE								
< 65	162	1 (0.6)	N.A.	143	1 (0.7)	N.A.	1.06 (0.07, 16.90) 0.9685	
>= 65	170	8 (4.7)	N.A.	182	12 (6.6)	N.A.	0.79 (0.32, 1.95) 0.6116	0.9915
SEX								
MALE	269	9 (3.3)	N.A.	269	12 (4.5)	N.A.	0.82 (0.34, 1.95) 0.6532	
FEMALE	63	0	N.E.	56	1 (1.8)	N.A.	N.E. 0.3006	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2943
HBV	98	1 (1.0)	N.A.	95	5 (5.3)	N.A.	0.21 (0.02, 1.79) 0.1145	
HCV	27	0	N.E.	25	2 (8.0)	N.A. (15.44, N.A.)	N.E. 0.1780	
UNINFECTED	207	8 (3.9)	N.A.	205	6 (2.9)	N.A.	1.43 (0.49, 4.14) 0.5099	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Malaise

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7886
PRESENT	204	3 (1.5)	N.A.	199	5 (2.5)	N.A.	0.61 (0.14, 2.59) 0.4982	
ABSENT	128	6 (4.7)	N.A.	126	8 (6.3)	N.A.	0.80 (0.28, 2.32) 0.6842	
BASELINE ALPHA-- FETOPROTEIN								0.4749
< 400 NG/ML	224	5 (2.2)	N.A.	217	9 (4.1)	N.A.	0.57 (0.19, 1.70) 0.3069	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	4 (3.7)	N.A.	1.08 (0.27, 4.38) 0.9115	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	7 (2.1)	N.A.	325	19 (5.8)	N.A.	0.38 (0.16, 0.92) 0.0257	0.4751
AGE < 65	162	2 (1.2)	N.A.	143	7 (4.9)	N.A.	0.23 (0.05, 1.14) 0.0508	
>= 65	170	5 (2.9)	N.A.	182	12 (6.6)	N.A.	0.55 (0.19, 1.55) 0.2486	
SEX								0.5291
MALE	269	4 (1.5)	N.A.	269	14 (5.2)	N.A.	0.29 (0.10, 0.90) 0.0235	
FEMALE	63	3 (4.8)	N.A.	56	5 (8.9)	N.A.	0.60 (0.14, 2.49) 0.4731	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9999
HBV	98	0	N.E.	95	5 (5.3)	N.A.	N.E. 0.0222	
HCV	27	0	N.E.	25	1 (4.0)	N.A. (22.51, N.A.)	N.E. 0.3173	
UNINFECTED	207	7 (3.4)	N.A.	205	13 (6.3)	N.A.	0.60 (0.24, 1.51) 0.2717	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Mucosal Inflammation

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5529
PRESENT	204	4 (2.0)	N.A.	199	13 (6.5)	N.A.	0.32 (0.11, 1.00) 0.0382	
ABSENT	128	3 (2.3)	N.A.	126	6 (4.8)	N.A.	0.53 (0.13, 2.15) 0.3664	
BASELINE ALPHA-- FETOPROTEIN								0.5337
< 400 NG/ML	224	6 (2.7)	N.A.	217	14 (6.5)	N.A.	0.44 (0.17, 1.15) 0.0846	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	5 (4.6)	N.A.	0.24 (0.03, 2.04) 0.1536	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	155 (46.7)	6.05 (4.21, 10.18)	325	151 (46.5)	7.62 (5.55, 13.57)	1.00 (0.80, 1.25) 0.9945	0.7198
AGE								
< 65	162	70 (43.2)	7.39 (4.27, N.A.)	143	60 (42.0)	10.78 (6.51, N.A.)	0.98 (0.70, 1.39) 0.9278	
>= 65	170	85 (50.0)	4.76 (2.56, 7.59)	182	91 (50.0)	6.21 (4.17, 11.53)	1.05 (0.78, 1.41) 0.7478	0.2918
SEX								
MALE	269	123 (45.7)	6.57 (4.63, 11.47)	269	127 (47.2)	7.33 (4.63, 13.57)	0.95 (0.74, 1.21) 0.6649	
FEMALE	63	32 (50.8)	3.75 (2.46, N.A.)	56	24 (42.9)	11.53 (5.52, 14.69)	1.29 (0.76, 2.19) 0.3519	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9328
HBV	98	30 (30.6)	N.A. (5.59, N.A.)	95	32 (33.7)	18.50 (10.15, N.A.)	0.92 (0.56, 1.51) 0.7469	
HCV	27	15 (55.6)	7.36 (2.86, 11.47)	25	16 (64.0)	4.63 (2.10, 13.60)	1.01 (0.50, 2.05) 0.9708	
UNINFECTED	207	110 (53.1)	4.76 (2.79, 6.70)	205	103 (50.2)	6.21 (3.88, 10.12)	1.03 (0.78, 1.35) 0.8350	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5494
PRESENT	204	98 (48.0)	4.83 (3.19, 10.18)	199	92 (46.2)	6.74 (4.57, 13.34)	1.06 (0.79, 1.40) 0.7052	
ABSENT	128	57 (44.5)	7.36 (4.73, N.A.)	126	59 (46.8)	10.78 (4.80, 14.69)	0.92 (0.64, 1.33) 0.6626	
BASELINE ALPHA-- FETOPROTEIN								0.1056
< 400 NG/ML	224	103 (46.0)	7.29 (4.73, 15.74)	217	106 (48.8)	6.44 (3.88, 14.69)	0.88 (0.67, 1.15) 0.3612	
>= 400 NG/ML	108	52 (48.1)	4.21 (2.50, 11.47)	108	45 (41.7)	7.62 (6.21, 13.60)	1.32 (0.88, 1.97) 0.1767	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	59 (17.8)	N.A.	325	92 (28.3)	25.23 (18.20, N.A.)	0.64 (0.46, 0.89) 0.0069	0.2318
AGE								
< 65	162	22 (13.6)	N.A.	143	36 (25.2)	N.A. (18.20, N.A.)	0.51 (0.30, 0.87) 0.0119	
>= 65	170	37 (21.8)	N.A.	182	56 (30.8)	25.23 (13.67, N.A.)	0.78 (0.51, 1.18) 0.2333	0.0968
SEX								
MALE	269	45 (16.7)	N.A.	269	80 (29.7)	25.23 (20.17, N.A.)	0.56 (0.39, 0.81) 0.0019	
FEMALE	63	14 (22.2)	N.A.	56	12 (21.4)	18.20 (11.53, N.A.)	1.17 (0.54, 2.53) 0.6955	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1844
HBV	98	8 (8.2)	N.A.	95	21 (22.1)	N.A. (18.20, N.A.)	0.35 (0.16, 0.80) 0.0094	
HCV	27	2 (7.4)	N.A.	25	8 (32.0)	N.A. (4.80, N.A.)	0.31 (0.07, 1.47) 0.1184	
UNINFECTED	207	49 (23.7)	N.A.	205	63 (30.7)	25.23 (13.67, N.A.)	0.78 (0.53, 1.13) 0.1910	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Decreased Appetite

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8149
PRESENT	204	39 (19.1)	N.A.	199	58 (29.1)	20.17 (11.53, N.A.)	0.65 (0.43, 0.98) 0.0389	
ABSENT	128	20 (15.6)	N.A.	126	34 (27.0)	25.23 (20.30, N.A.)	0.61 (0.35, 1.06) 0.0769	
BASELINE ALPHA-- FETOPROTEIN								0.4843
< 400 NG/ML	224	46 (20.5)	N.A.	217	66 (30.4)	25.23 (18.20, N.A.)	0.68 (0.47, 0.99) 0.0457	
>= 400 NG/ML	108	13 (12.0)	N.A.	108	26 (24.1)	N.A. (10.68, N.A.)	0.51 (0.26, 0.99) 0.0423	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypoalbuminaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	31 (9.3)	N.A.	325	35 (10.8)	N.A.	1.04 (0.64, 1.70) 0.8757	0.9095
AGE								
< 65	162	17 (10.5)	N.A.	143	16 (11.2)	N.A.	1.14 (0.56, 2.31) 0.7153	
>= 65	170	14 (8.2)	N.A.	182	19 (10.4)	(25.13, N.A.) N.A.	0.95 (0.48, 1.90) 0.8869	0.5835
SEX								
MALE	269	26 (9.7)	N.A.	269	28 (10.4)	N.A.	1.04 (0.61, 1.78) 0.8729	
FEMALE	63	5 (7.9)	N.A.	56	7 (12.5)	(25.00, N.A.) N.A.	1.01 (0.29, 3.51) 0.9818	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypoalbuminaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3367
HBV	98	10 (10.2)	N.A.	95	6 (6.3)	N.A. (25.00, N.A.)	2.28 (0.78, 6.67) 0.1221	
HCV	27	3 (11.1)	N.A.	25	5 (20.0)	N.A. (13.60, N.A.)	0.69 (0.17, 2.90) 0.6120	
UNINFECTED	207	18 (8.7)	N.A.	205	24 (11.7)	N.A.	0.85 (0.46, 1.58) 0.6068	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypoalbuminaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8198
PRESENT	204	19 (9.3)	N.A.	199	22 (11.1)	N.A.	1.00 (0.53, 1.85) 0.9885	
ABSENT	128	12 (9.4)	N.A.	126	13 (10.3)	N.A.	1.13 (0.51, 2.51) 0.7727	
BASELINE ALPHA-- FETOPROTEIN								0.6794
< 400 NG/ML	224	21 (9.4)	N.A.	217	25 (11.5)	N.A.	0.91 (0.51, 1.62) 0.7433	
>= 400 NG/ML	108	10 (9.3)	N.A.	108	10 (9.3)	N.A. (25.00, N.A.)	1.46 (0.57, 3.71) 0.4232	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyponatraemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	30 (9.0)	N.A.	325	14 (4.3)	N.A.	2.44 (1.29, 4.60) 0.0046	0.3357
AGE								
< 65	162	13 (8.0)	N.A.	143	3 (2.1)	N.A.	4.16 (1.18, 14.64) 0.0159	
>= 65	170	17 (10.0)	N.A.	182	11 (6.0)	N.A.	2.05 (0.96, 4.39) 0.0581	0.5173
SEX								
MALE	269	25 (9.3)	N.A.	269	11 (4.1)	N.A.	2.69 (1.32, 5.47) 0.0045	
FEMALE	63	5 (7.9)	N.A.	56	3 (5.4)	N.A.	1.47 (0.35, 6.20) 0.5946	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyponatraemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2988
HBV	98	3 (3.1)	N.A.	95	4 (4.2)	N.A.	0.86 (0.19, 3.84) 0.8426	
HCV	27	3 (11.1)	N.A.	25	1 (4.0)	N.A.	3.56 (0.37, 34.41) 0.2424	
UNINFECTED	207	24 (11.6)	N.A.	205	9 (4.4)	N.A.	3.02 (1.40, 6.52) 0.0030	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyponatraemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9507
PRESENT	204	20 (9.8)	N.A.	199	9 (4.5)	N.A.	2.48 (1.13, 5.46) 0.0197	
ABSENT	128	10 (7.8)	N.A.	126	5 (4.0)	N.A.	2.31 (0.79, 6.77) 0.1163	
BASELINE ALPHA-- FETOPROTEIN								0.0569
< 400 NG/ML	224	22 (9.8)	N.A.	217	6 (2.8)	N.A.	4.08 (1.65, 10.08) 0.0010	
>= 400 NG/ML	108	8 (7.4)	N.A.	108	8 (7.4)	N.A.	1.21 (0.45, 3.22) 0.7073	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	29 (8.7)	N.A.	325	8 (2.5)	N.A.	4.12 (1.88, 9.02) 0.0001	0.9990
AGE								
< 65	162	13 (8.0)	N.A.	143	3 (2.1)	N.A.	4.08 (1.16, 14.36) 0.0175	
>= 65	170	16 (9.4)	N.A.	182	5 (2.7)	N.A.	4.29 (1.57, 11.71) 0.0020	0.6819
SEX								
MALE	269	23 (8.6)	N.A.	269	7 (2.6)	N.A.	3.83 (1.64, 8.93) 0.0008	
FEMALE	63	6 (9.5)	N.A.	56	1 (1.8)	N.A.	6.02 (0.72, 49.95) 0.0584	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6431
HBV	98	5 (5.1)	N.A.	95	1 (1.1)	N.A.	5.29 (0.61, 45.58) 0.0904	
HCV	27	3 (11.1)	N.A. (7.59, N.A.)	25	2 (8.0)	N.A.	2.11 (0.35, 12.78) 0.4066	
UNINFECTED	207	21 (10.1)	N.A.	205	5 (2.4)	N.A.	4.80 (1.81, 12.73) 0.0005	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4121
PRESENT	204	19 (9.3)	N.A.	199	4 (2.0)	N.A.	5.53 (1.88, 16.27) 0.0005	
ABSENT	128	10 (7.8)	N.A.	126	4 (3.2)	N.A.	2.72 (0.85, 8.70) 0.0779	
BASELINE ALPHA-- FETOPROTEIN								0.3418
< 400 NG/ML	224	17 (7.6)	N.A.	217	6 (2.8)	N.A.	3.05 (1.20, 7.75) 0.0136	
>= 400 NG/ML	108	12 (11.1)	N.A.	108	2 (1.9)	N.A.	7.80 (1.74, 34.89) 0.0015	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypokalaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	17 (5.1)	24.87 (N.A., N.A.)	325	10 (3.1)	N.A.	2.36 (1.03, 5.42) 0.0368	0.7984
AGE								
< 65	162	9 (5.6)	N.A.	143	4 (2.8)	N.A. (24.90, N.A.)	2.88 (0.78, 10.66) 0.0963	
>= 65	170	8 (4.7)	24.87 (N.A., N.A.)	182	6 (3.3)	N.A.	1.97 (0.66, 5.88) 0.2148	0.9225
SEX								
MALE	269	10 (3.7)	24.87 (N.A., N.A.)	269	6 (2.2)	N.A.	2.33 (0.82, 6.67) 0.1043	
FEMALE	63	7 (11.1)	N.A.	56	4 (7.1)	N.A. (24.90, N.A.)	2.24 (0.58, 8.66) 0.2307	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypokalaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6823
HBV	98	6 (6.1)	N.A.	95	2 (2.1)	N.A.	3.53 (0.71, 17.52) 0.0992	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	11 (5.3)	24.87 (N.A., N.A.)	205	8 (3.9)	N.A.	1.96 (0.74, 5.22) 0.1683	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypokalaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9303
PRESENT	204	11 (5.4)	24.87 (N.A., N.A.)	199	6 (3.0)	N.A.	2.31 (0.83, 6.44) 0.1001	
ABSENT	128	6 (4.7)	N.A.	126	4 (3.2)	N.A.	2.36 (0.59, 9.44) 0.2109	
BASELINE ALPHA-- FETOPROTEIN								0.3795
< 400 NG/ML	224	11 (4.9)	24.87 (N.A., N.A.)	217	8 (3.7)	N.A.	1.71 (0.67, 4.36) 0.2549	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	2 (1.9)	N.A. (24.90, N.A.)	7.07 (0.85, 58.79) 0.0350	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperkalaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	15 (4.6)	N.A.	0.85 (0.40, 1.82) 0.6747	0.5943
AGE								
< 65	162	7 (4.3)	N.A.	143	6 (4.2)	N.A.	1.08 (0.36, 3.23) 0.8874	
>= 65	170	5 (2.9)	N.A. (23.95, N.A.)	182	9 (4.9)	N.A.	0.67 (0.22, 2.04) 0.4824	0.2555
SEX								
MALE	269	9 (3.3)	N.A.	269	14 (5.2)	N.A.	0.70 (0.30, 1.62) 0.3967	
FEMALE	63	3 (4.8)	N.A.	56	1 (1.8)	N.A.	2.87 (0.30, 27.64) 0.3395	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperkalaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6789
HBV	98	4 (4.1)	N.A.	95	3 (3.2)	N.A.	1.54 (0.34, 6.88) 0.5725	
HCV	27	2 (7.4)	N.A.	25	4 (16.0)	N.A.	0.58 (0.11, 3.19) 0.5292	
UNINFECTED	207	6 (2.9)	N.A.	205	8 (3.9)	N.A.	0.71 (0.24, 2.07) 0.5276	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperkalaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7935
PRESENT	204	8 (3.9)	N.A.	199	9 (4.5)	N.A.	0.87 (0.33, 2.26) 0.7693	
ABSENT	128	4 (3.1)	N.A.	126	6 (4.8)	N.A.	0.78 (0.22, 2.77) 0.6993	
BASELINE ALPHA-- FETOPROTEIN								0.3774
< 400 NG/ML	224	9 (4.0)	N.A.	217	9 (4.1)	N.A.	1.06 (0.42, 2.67) 0.9093	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	6 (5.6)	N.A.	0.58 (0.14, 2.33) 0.4351	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	19 (5.8)	N.A.	0.63 (0.30, 1.34) 0.2265	0.7097
AGE								
< 65	162	5 (3.1)	N.A.	143	6 (4.2)	N.A.	0.93 (0.27, 3.22) 0.9126	
>= 65	170	6 (3.5)	N.A.	182	13 (7.1)	(27.86, N.A.) N.A.	0.52 (0.20, 1.40) 0.1917	0.6903
SEX								
MALE	269	8 (3.0)	N.A.	269	13 (4.8)	N.A.	0.67 (0.27, 1.66) 0.3866	
FEMALE	63	3 (4.8)	N.A.	56	6 (10.7)	N.A.	0.48 (0.12, 1.93) 0.2917	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5101
HBV	98	1 (1.0)	N.A.	95	4 (4.2)	N.A.	0.28 (0.03, 2.48) 0.2195	
HCV	27	1 (3.7)	N.A.	25	4 (16.0)	27.86 (N.A., N.A.)	0.41 (0.04, 3.95) 0.4260	
UNINFECTED	207	9 (4.3)	N.A.	205	11 (5.4)	N.A.	0.83 (0.34, 2.01) 0.6746	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypomagnesaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9506
PRESENT	204	7 (3.4)	N.A.	199	12 (6.0)	N.A.	0.56 (0.22, 1.43) 0.2186	
ABSENT	128	4 (3.1)	N.A.	126	7 (5.6)	N.A. (27.86, N.A.)	0.78 (0.22, 2.75) 0.6946	
BASELINE ALPHA-- FETOPROTEIN								0.8425
< 400 NG/ML	224	7 (3.1)	N.A.	217	13 (6.0)	N.A.	0.58 (0.23, 1.50) 0.2584	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	6 (5.6)	N.A.	0.77 (0.22, 2.74) 0.6863	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypophosphataemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	5 (1.5)	N.A.	325	12 (3.7)	N.A.	0.46 (0.16, 1.30) 0.1335	0.4363
AGE								
< 65	162	1 (0.6)	N.A.	143	4 (2.8)	N.A.	0.24 (0.03, 2.12) 0.1616	
>= 65	170	4 (2.4)	N.A.	182	8 (4.4)	N.A.	0.65 (0.19, 2.15) 0.4708	0.9550
SEX								
MALE	269	4 (1.5)	N.A.	269	10 (3.7)	N.A.	0.44 (0.14, 1.41) 0.1559	
FEMALE	63	1 (1.6)	N.A.	56	2 (3.6)	N.A.	0.53 (0.05, 5.81) 0.5936	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypophosphataemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8654
HBV	98	1 (1.0)	N.A.	95	1 (1.1)	N.A.	1.14 (0.07, 18.33) 0.9247	
HCV	27	0	N.E.	25	2 (8.0)	N.A.	N.E. 0.2297	
UNINFECTED	207	4 (1.9)	N.A.	205	9 (4.4)	N.A.	0.47 (0.14, 1.53) 0.1983	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hypophosphataemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	3 (1.5)	N.M.E.	199	6 (3.0)	N.M.E.	N.M.E.	
ABSENT	128	2 (1.6)	N.M.E.	126	6 (4.8)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								0.5287
< 400 NG/ML	224	3 (1.3)	N.A.	217	9 (4.1)	N.A.	0.37 (0.10, 1.35) 0.1159	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	3 (2.8)	N.A.	0.81 (0.13, 4.88) 0.8187	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	130 (39.2)	12.75 (9.13, 17.18)	325	101 (31.1)	16.30 (13.83, 25.79)	1.38 (1.06, 1.79) 0.0170	0.1377
AGE								
< 65	162	68 (42.0)	11.14 (8.31, 14.65)	143	41 (28.7)	22.11 (14.55, N.A.)	1.64 (1.11, 2.43) 0.0121	
>= 65	170	62 (36.5)	17.05 (6.54, N.A.)	182	60 (33.0)	15.57 (12.12, N.A.)	1.18 (0.82, 1.69) 0.3648	0.8364
SEX								
MALE	269	108 (40.1)	12.75 (9.03, 17.68)	269	84 (31.2)	17.61 (13.83, 25.79)	1.39 (1.04, 1.86) 0.0244	
FEMALE	63	22 (34.9)	12.91 (4.47, N.A.)	56	17 (30.4)	13.83 (8.05, N.A.)	1.32 (0.70, 2.50) 0.3891	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3136
HBV	98	23 (23.5)	N.A. (14.59, N.A.)	95	26 (27.4)	26.71 (13.83, N.A.)	0.95 (0.54, 1.68) 0.8747	
HCV	27	14 (51.9)	7.29 (2.04, 15.70)	25	13 (52.0)	16.16 (3.52, 17.61)	1.35 (0.62, 2.93) 0.4516	
UNINFECTED	207	93 (44.9)	9.36 (5.26, 13.86)	205	62 (30.2)	15.57 (12.02, N.A.)	1.58 (1.14, 2.19) 0.0056	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8778
PRESENT	204	82 (40.2)	11.93 (7.52, 17.05)	199	63 (31.7)	16.16 (12.02, N.A.)	1.33 (0.96, 1.86) 0.0878	
ABSENT	128	48 (37.5)	15.70 (8.84, N.A.)	126	38 (30.2)	17.61 (12.91, N.A.)	1.41 (0.92, 2.16) 0.1158	
BASELINE ALPHA-- FETOPROTEIN								0.0475*
< 400 NG/ML	224	93 (41.5)	13.67 (9.03, 17.68)	217	62 (28.6)	22.11 (15.57, N.A.)	1.65 (1.19, 2.28) 0.0023	
>= 400 NG/ML	108	37 (34.3)	10.94 (7.29, N.A.)	108	39 (36.1)	12.91 (8.74, 16.30)	0.94 (0.59, 1.49) 0.7923	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Covid-19

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva		Test for Interaction P-value (4)(5)
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)		
OVERALL	332	32 (9.6)	N.A.	325	19 (5.8)	N.A.	1.55 (0.87, 2.76) 0.1323		
AGE									0.2285
< 65	162	21 (13.0)	N.A.	143	8 (5.6)	N.A.	2.04 (0.90, 4.65) 0.0826		
>= 65	170	11 (6.5)	N.A.	182	11 (6.0)	(20.34, N.A.) N.A.	1.08 (0.46, 2.55) 0.8568		
SEX									0.8377
MALE	269	24 (8.9)	N.A.	269	15 (5.6)	N.A.	1.50 (0.78, 2.90) 0.2208		
FEMALE	63	8 (12.7)	N.A. (17.22, N.A.)	56	4 (7.1)	N.A. (17.91, N.A.)	1.69 (0.50, 5.70) 0.3906		

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Covid-19

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7157
HBV	98	8 (8.2)	N.A. (18.17, N.A.)	95	4 (4.2)	N.A.	2.11 (0.63, 7.03) 0.2099	
HCV	27	5 (18.5)	N.A. (7.29, N.A.)	25	3 (12.0)	20.34 (17.61, N.A.)	1.93 (0.45, 8.22) 0.3645	
UNINFECTED	207	19 (9.2)	N.A.	205	12 (5.9)	N.A.	1.39 (0.66, 2.92) 0.3825	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Covid-19

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2422
PRESENT	204	23 (11.3)	N.A.	199	10 (5.0)	N.A.	2.14 (1.01, 4.55) 0.0423	
ABSENT	128	9 (7.0)	N.A.	126	9 (7.1)	N.A. (20.34, N.A.)	0.92 (0.36, 2.35) 0.8637	
BASELINE ALPHA-- FETOPROTEIN								0.5707
< 400 NG/ML	224	21 (9.4)	N.A.	217	12 (5.5)	N.A.	1.72 (0.84, 3.52) 0.1352	
>= 400 NG/ML	108	11 (10.2)	N.A.	108	7 (6.5)	N.A. (16.30, N.A.)	1.19 (0.45, 3.18) 0.7206	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Pneumonia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	17 (5.1)	N.A.	325	7 (2.2)	N.A.	2.39 (0.98, 5.81) 0.0482	0.7522
AGE								
< 65	162	4 (2.5)	N.A.	143	1 (0.7)	N.A.	3.26 (0.36, 29.46) 0.2668	
>= 65	170	13 (7.6)	N.A.	182	6 (3.3)	N.A.	2.44 (0.92, 6.51) 0.0651	0.1333
SEX								
MALE	269	16 (5.9)	N.A.	269	5 (1.9)	N.A.	3.31 (1.20, 9.12) 0.0141	
FEMALE	63	1 (1.6)	N.A.	56	2 (3.6)	N.A. (18.73, N.A.)	0.42 (0.04, 4.71) 0.4692	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Pneumonia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8699
HBV	98	3 (3.1)	N.A.	95	2 (2.1)	N.A.	1.64 (0.27, 9.88) 0.5827	
HCV	27	2 (7.4)	N.A.	25	1 (4.0)	N.A. (14.42, N.A.)	2.40 (0.22, 26.56) 0.4606	
UNINFECTED	207	12 (5.8)	N.A.	205	4 (2.0)	N.A.	2.70 (0.86, 8.54) 0.0786	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

- (1) KME of median time to first AE.
- (2) Hazard ratio from unstratified Cox proportional hazard model.
- (3) p-value from unstratified log-rank test.
- (4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Pneumonia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7678
PRESENT	204	14 (6.9)	N.A.	199	6 (3.0)	N.A.	2.21 (0.84, 5.82) 0.1013	
ABSENT	128	3 (2.3)	N.A.	126	1 (0.8)	N.A.	3.15 (0.32, 30.62) 0.2975	
BASELINE ALPHA-- FETOPROTEIN								0.2101
< 400 NG/ML	224	12 (5.4)	N.A.	217	3 (1.4)	N.A.	4.03 (1.13, 14.38) 0.0203	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	4 (3.7)	N.A. (18.73, N.A.)	1.10 (0.28, 4.27) 0.8910	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Urinary Tract Infection

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	14 (4.2)	26.48 (N.A., N.A.)	325	21 (6.5)	N.A.	0.80 (0.40, 1.61) 0.5292	0.2085
AGE < 65	162	7 (4.3)	N.A.	143	5 (3.5)	N.A.	1.27 (0.40, 4.03) 0.6835	
>= 65	170	7 (4.1)	26.48 (N.A., N.A.)	182	16 (8.8)	N.A. (25.79, N.A.)	0.62 (0.25, 1.56) 0.3096	
SEX								0.3229
MALE	269	11 (4.1)	26.48 (N.A., N.A.)	269	14 (5.2)	N.A. (30.39, N.A.)	1.05 (0.46, 2.41) 0.9080	
FEMALE	63	3 (4.8)	N.A.	56	7 (12.5)	N.A.	0.35 (0.09, 1.41) 0.1252	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Urinary Tract Infection

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8501
HBV	98	2 (2.0)	N.A.	95	2 (2.1)	N.A.	0.99 (0.14, 7.20) 0.9901	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E. 0.2689	
UNINFECTED	207	11 (5.3)	26.48 (N.A., N.A.)	205	19 (9.3)	N.A. (30.39, N.A.)	0.69 (0.32, 1.48) 0.3370	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations. PT: Urinary Tract Infection

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3445
PRESENT	204	8 (3.9)	N.A.	199	15 (7.5)	N.A. (30.39, N.A.)	0.55 (0.23, 1.33) 0.1800	
ABSENT	128	6 (4.7)	26.48 (N.A., N.A.)	126	6 (4.8)	N.A. (25.79, N.A.)	1.46 (0.45, 4.76) 0.5259	
BASELINE ALPHA-- FETOPROTEIN								0.1795
< 400 NG/ML	224	9 (4.0)	26.48 (N.A., N.A.)	217	9 (4.1)	N.A.	1.35 (0.51, 3.52) 0.5436	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	12 (11.1)	30.39 (18.66, N.A.)	0.42 (0.14, 1.24) 0.1062	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	103 (31.0)	23.69 (13.08, N.A.)	325	113 (34.8)	N.A. (16.13, N.A.)	0.85 (0.65, 1.12) 0.2536	0.6495
AGE								
< 65	162	46 (28.4)	24.11 (15.70, N.A.)	143	47 (32.9)	N.A. (13.83, N.A.)	0.80 (0.53, 1.21) 0.2929	
>= 65	170	57 (33.5)	14.00 (9.86, N.A.)	182	66 (36.3)	20.37 (11.47, N.A.)	0.91 (0.64, 1.30) 0.6174	0.6112
SEX								
MALE	269	85 (31.6)	23.69 (13.08, N.A.)	269	91 (33.8)	N.A. (20.34, N.A.)	0.89 (0.66, 1.20) 0.4470	
FEMALE	63	18 (28.6)	21.19 (6.54, N.A.)	56	22 (39.3)	11.40 (5.75, N.A.)	0.73 (0.39, 1.36) 0.3227	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7959
HBV	98	28 (28.6)	23.69 (11.33, N.A.)	95	29 (30.5)	N.A. (13.83, N.A.)	0.91 (0.54, 1.53) 0.7178	
HCV	27	8 (29.6)	24.11 (6.83, N.A.)	25	7 (28.0)	N.A. (8.57, N.A.)	1.19 (0.43, 3.31) 0.7318	
UNINFECTED	207	67 (32.4)	18.46 (11.96, N.A.)	205	77 (37.6)	20.37 (7.52, N.A.)	0.80 (0.58, 1.12) 0.1911	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1380
PRESENT	204	67 (32.8)	16.95 (11.33, 24.11)	199	63 (31.7)	N.A. (13.83, N.A.)	1.01 (0.71, 1.42) 0.9642	
ABSENT	128	36 (28.1)	N.A. (15.70, N.A.)	126	50 (39.7)	20.34 (7.52, N.A.)	0.66 (0.43, 1.01) 0.0550	
BASELINE ALPHA-- FETOPROTEIN								0.0030*
< 400 NG/ML	224	83 (37.1)	14.00 (9.46, 23.79)	217	73 (33.6)	N.A. (20.34, N.A.)	1.11 (0.81, 1.52) 0.5069	
>= 400 NG/ML	108	20 (18.5)	N.A.	108	40 (37.0)	16.13 (9.10, N.A.)	0.43 (0.25, 0.73) 0.0016	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	44 (13.3)	N.A. (24.11, N.A.)	325	23 (7.1)	N.A.	2.11 (1.27, 3.50) 0.0032	0.7870
AGE < 65	162	19 (11.7)	N.A. (24.11, N.A.)	143	9 (6.3)	N.A.	1.97 (0.89, 4.39) 0.0889	
>= 65	170	25 (14.7)	N.A. (23.79, N.A.)	182	14 (7.7)	N.A.	2.28 (1.18, 4.40) 0.0114	
SEX								0.0323*
MALE	269	40 (14.9)	24.11 (24.11, N.A.)	269	17 (6.3)	N.A.	2.76 (1.56, 4.90) 0.0003	
FEMALE	63	4 (6.3)	N.A.	56	6 (10.7)	N.A.	0.57 (0.16, 2.03) 0.3792	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5548
HBV	98	11 (11.2)	N.A. (23.69, N.A.)	95	7 (7.4)	N.A.	1.69 (0.65, 4.37) 0.2723	
HCV	27	3 (11.1)	24.11 (N.A., N.A.)	25	3 (12.0)	N.A. (14.42, N.A.)	1.18 (0.24, 5.86) 0.8434	
UNINFECTED	207	30 (14.5)	N.A.	205	13 (6.3)	N.A.	2.49 (1.29, 4.78) 0.0048	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Cough

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.6404
PRESENT	204	27 (13.2)	24.11 (23.79, N.A.)	199	15 (7.5)	N.A.	1.96 (1.03, 3.70) 0.0355	
ABSENT	128	17 (13.3)	N.A.	126	8 (6.3)	N.A.	2.35 (1.01, 5.45) 0.0404	
BASELINE ALPHA-- FETOPROTEIN								0.0582
< 400 NG/ML	224	37 (16.5)	24.11 (23.79, N.A.)	217	15 (6.9)	N.A.	2.84 (1.55, 5.20) 0.0004	
>= 400 NG/ML	108	7 (6.5)	N.A.	108	8 (7.4)	N.A.	0.88 (0.31, 2.46) 0.8042	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	28 (8.4)	N.A.	325	15 (4.6)	N.A.	2.08 (1.11, 3.90) 0.0192	0.7074
AGE								
< 65	162	15 (9.3)	N.A.	143	6 (4.2)	N.A.	2.48 (0.96, 6.39) 0.0522	
>= 65	170	13 (7.6)	N.A.	182	9 (4.9)	N.A.	1.80 (0.77, 4.23) 0.1684	0.3511
SEX								
MALE	269	20 (7.4)	N.A.	269	13 (4.8)	N.A.	1.77 (0.88, 3.57) 0.1041	
FEMALE	63	8 (12.7)	N.A.	56	2 (3.6)	N.A.	4.00 (0.85, 18.86) 0.0576	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4674
HBV	98	8 (8.2)	N.A.	95	6 (6.3)	N.A.	1.57 (0.54, 4.52) 0.4024	
HCV	27	3 (11.1)	N.A.	25	3 (12.0)	N.A. (14.42, N.A.)	1.22 (0.25, 6.04) 0.8097	
UNINFECTED	207	17 (8.2)	N.A.	205	6 (2.9)	N.A.	3.11 (1.22, 7.90) 0.0121	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dyspnoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0810
PRESENT	204	15 (7.4)	N.A.	199	12 (6.0)	N.A.	1.33 (0.62, 2.84) 0.4643	
ABSENT	128	13 (10.2)	N.A.	126	3 (2.4)	N.A.	5.12 (1.46, 17.99) 0.0045	
BASELINE ALPHA-- FETOPROTEIN								0.0244*
< 400 NG/ML	224	24 (10.7)	N.A.	217	8 (3.7)	N.A.	3.39 (1.52, 7.56) 0.0015	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	7 (6.5)	N.A.	0.61 (0.18, 2.09) 0.4221	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	N.A.	325	1 (0.3)	N.A.	12.07 (1.54, 94.32) 0.0024	
AGE								N.M.E.
< 65	162	6 (3.7)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	4 (2.4)	N.M.E.	182	1 (0.5)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	269	8 (3.0)	N.M.E.	269	1 (0.4)	N.M.E.	N.M.E.	
FEMALE	63	2 (3.2)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	4 (4.1)	N.M.E.	95	1 (1.1)	N.M.E.	N.M.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	5 (2.4)	N.M.E.	205	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Pneumonitis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	7 (3.4)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	3 (2.3)	N.M.E.	126	1 (0.8)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								N.M.E.
< 400 NG/ML	224	8 (3.6)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	2 (1.9)	N.M.E.	108	1 (0.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	8 (2.4)	N.A.	325	20 (6.2)	N.A.	0.39 (0.17, 0.89) 0.0214	0.8231
AGE								
< 65	162	5 (3.1)	N.A.	143	12 (8.4)	N.A.	0.35 (0.12, 1.01) 0.0432	
>= 65	170	3 (1.8)	N.A.	182	8 (4.4)	N.A.	0.41 (0.11, 1.56) 0.1772	0.5458
SEX								
MALE	269	7 (2.6)	N.A.	269	16 (5.9)	N.A.	0.44 (0.18, 1.07) 0.0635	
FEMALE	63	1 (1.6)	N.A.	56	4 (7.1)	N.A.	0.23 (0.03, 2.08) 0.1541	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3842
HBV	98	3 (3.1)	N.A.	95	3 (3.2)	N.A.	0.99 (0.20, 4.94) 0.9858	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	5 (2.4)	N.A.	205	17 (8.3)	N.A.	0.28 (0.10, 0.76) 0.0080	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Epistaxis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7931
PRESENT	204	5 (2.5)	N.A.	199	11 (5.5)	N.A.	0.48 (0.17, 1.38) 0.1652	
ABSENT	128	3 (2.3)	N.A.	126	9 (7.1)	N.A. (22.51, N.A.)	0.31 (0.08, 1.15) 0.0648	
BASELINE ALPHA-- FETOPROTEIN								0.5310
< 400 NG/ML	224	5 (2.2)	N.A.	217	15 (6.9)	N.A.	0.31 (0.11, 0.88) 0.0199	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	5 (4.6)	N.A.	0.66 (0.16, 2.78) 0.5687	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dysphonia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	7 (2.1)	N.A.	325	60 (18.5)	N.A.	0.11 (0.05, 0.25) <0.0001	0.6095
AGE								
< 65	162	2 (1.2)	N.A.	143	20 (14.0)	N.A.	0.09 (0.02, 0.37) <0.0001	
>= 65	170	5 (2.9)	N.A.	182	40 (22.0)	N.A.	0.14 (0.05, 0.34) <0.0001	0.9874
SEX								
MALE	269	7 (2.6)	N.A.	269	53 (19.7)	N.A.	0.13 (0.06, 0.28) <0.0001	0.0064
FEMALE	63	0	N.E.	56	7 (12.5)	N.A.	N.E. 0.0064	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dysphonia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9935
HBV	98	2 (2.0)	N.A.	95	15 (15.8)	N.A.	0.12 (0.03, 0.54) 0.0010	
HCV	27	0	N.E.	25	3 (12.0)	N.A.	N.E. 0.0830	
UNINFECTED	207	5 (2.4)	N.A.	205	42 (20.5)	N.A.	0.12 (0.05, 0.29) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders. PT: Dysphonia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4119
PRESENT	204	2 (1.0)	N.A.	199	28 (14.1)	N.A.	0.07 (0.02, 0.29) <0.0001	
ABSENT	128	5 (3.9)	N.A.	126	32 (25.4)	N.A.	0.15 (0.06, 0.38) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.9828
< 400 NG/ML	224	7 (3.1)	N.A.	217	41 (18.9)	N.A.	0.16 (0.07, 0.36) <0.0001	
>= 400 NG/ML	108	0	N.E.	108	19 (17.6)	N.A.	N.E. <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	102 (30.7)	24.54 (11.96, N.A.)	325	122 (37.5)	14.69 (8.51, 23.00)	0.84 (0.64, 1.10) 0.1966	0.9819
AGE								
< 65	162	53 (32.7)	N.A. (11.63, N.A.)	143	53 (37.1)	16.13 (6.01, N.A.)	0.84 (0.57, 1.23) 0.3690	
>= 65	170	49 (28.8)	24.54 (8.74, N.A.)	182	69 (37.9)	14.69 (7.85, N.A.)	0.85 (0.59, 1.23) 0.3798	0.1693
SEX								
MALE	269	75 (27.9)	24.54 (15.87, N.A.)	269	102 (37.9)	15.44 (7.85, 24.15)	0.76 (0.57, 1.03) 0.0801	
FEMALE	63	27 (42.9)	8.74 (3.12, N.A.)	56	20 (35.7)	20.53 (4.67, N.A.)	1.17 (0.65, 2.09) 0.5927	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7590
HBV	98	25 (25.5)	N.A. (15.87, N.A.)	95	30 (31.6)	24.15 (10.35, N.A.)	0.88 (0.51, 1.50) 0.6300	
HCV	27	8 (29.6)	13.47 (5.75, N.A.)	25	8 (32.0)	13.93 (6.77, N.A.)	1.20 (0.45, 3.21) 0.7166	
UNINFECTED	207	69 (33.3)	17.38 (8.34, N.A.)	205	84 (41.0)	10.12 (6.14, 23.00)	0.80 (0.58, 1.10) 0.1626	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.6235
PRESENT	204	62 (30.4)	24.54 (11.24, N.A.)	199	68 (34.2)	14.42 (7.85, N.A.)	0.92 (0.65, 1.30) 0.6488	
ABSENT	128	40 (31.3)	20.44 (9.03, N.A.)	126	54 (42.9)	16.13 (6.47, 23.00)	0.75 (0.50, 1.13) 0.1663	
BASELINE ALPHA-- FETOPROTEIN								0.3114
< 400 NG/ML	224	76 (33.9)	17.38 (8.25, N.A.)	217	85 (39.2)	16.13 (7.85, 24.18)	0.91 (0.67, 1.24) 0.5572	
>= 400 NG/ML	108	26 (24.1)	24.54 (13.47, N.A.)	108	37 (34.3)	13.93 (6.57, 20.53)	0.66 (0.40, 1.10) 0.1123	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	44 (13.3)	N.A.	325	43 (13.2)	N.A.	1.13 (0.74, 1.73) 0.5729	0.7153
AGE								
< 65	162	22 (13.6)	N.A.	143	20 (14.0)	N.A.	1.07 (0.58, 1.97) 0.8385	
>= 65	170	22 (12.9)	N.A.	182	23 (12.6)	N.A.	1.20 (0.67, 2.16) 0.5340	0.8725
SEX								
MALE	269	34 (12.6)	N.A.	269	35 (13.0)	N.A.	1.07 (0.67, 1.72) 0.7661	0.8725
FEMALE	63	10 (15.9)	N.A. (11.96, N.A.)	56	8 (14.3)	N.A. (26.68, N.A.)	1.35 (0.51, 3.55) 0.5426	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6520
HBV	98	10 (10.2)	N.A.	95	11 (11.6)	N.A. (26.68, N.A.)	1.09 (0.45, 2.63) 0.8438	
HCV	27	2 (7.4)	N.A. (11.96, N.A.)	25	4 (16.0)	N.A.	0.54 (0.10, 2.98) 0.4734	
UNINFECTED	207	32 (15.5)	N.A.	205	28 (13.7)	N.A.	1.20 (0.72, 2.00) 0.4732	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Arthralgia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9742
PRESENT	204	27 (13.2)	N.A.	199	26 (13.1)	N.A. (26.68, N.A.)	1.15 (0.67, 1.99) 0.6075	
ABSENT	128	17 (13.3)	N.A.	126	17 (13.5)	N.A.	1.10 (0.56, 2.15) 0.7846	
BASELINE ALPHA-- FETOPROTEIN								0.0765
< 400 NG/ML	224	35 (15.6)	N.A.	217	28 (12.9)	N.A.	1.46 (0.88, 2.41) 0.1383	
>= 400 NG/ML	108	9 (8.3)	N.A.	108	15 (13.9)	N.A. (15.44, N.A.)	0.55 (0.23, 1.27) 0.1526	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Back Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	24 (7.2)	24.54 (N.A., N.A.)	325	29 (8.9)	N.A.	0.98 (0.57, 1.69) 0.9306	0.5719
AGE < 65	162	12 (7.4)	N.A.	143	10 (7.0)	N.A.	1.13 (0.49, 2.62) 0.7730	
>= 65	170	12 (7.1)	24.54 (N.A., N.A.)	182	19 (10.4)	N.A.	0.89 (0.43, 1.86) 0.7613	
SEX								0.8782
MALE	269	19 (7.1)	24.54 (N.A., N.A.)	269	23 (8.6)	N.A.	1.02 (0.55, 1.89) 0.9506	
FEMALE	63	5 (7.9)	N.A.	56	6 (10.7)	N.A.	0.83 (0.25, 2.71) 0.7547	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Back Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6090
HBV	98	8 (8.2)	N.A.	95	7 (7.4)	N.A.	1.19 (0.43, 3.29) 0.7349	
HCV	27	2 (7.4)	N.A. (5.75, N.A.)	25	2 (8.0)	N.A. (13.86, N.A.)	1.57 (0.22, 11.14) 0.6504	
UNINFECTED	207	14 (6.8)	24.54 (N.A., N.A.)	205	20 (9.8)	N.A.	0.83 (0.41, 1.65) 0.5893	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Back Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4774
PRESENT	204	16 (7.8)	24.54 (N.A., N.A.)	199	16 (8.0)	N.A.	1.15 (0.57, 2.31) 0.7059	
ABSENT	128	8 (6.3)	N.A.	126	13 (10.3)	N.A.	0.75 (0.31, 1.82) 0.5251	
BASELINE ALPHA-- FETOPROTEIN								0.7639
< 400 NG/ML	224	18 (8.0)	N.A.	217	21 (9.7)	N.A.	1.00 (0.53, 1.89) 0.9892	
>= 400 NG/ML	108	6 (5.6)	24.54 (N.A., N.A.)	108	8 (7.4)	N.A.	0.88 (0.30, 2.61) 0.8204	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	20 (6.0)	N.A.	325	24 (7.4)	N.A.	0.87 (0.48, 1.57) 0.6408	0.3240
AGE								
< 65	162	15 (9.3)	N.A.	143	13 (9.1)	N.A.	1.05 (0.50, 2.21) 0.9028	
>= 65	170	5 (2.9)	N.A.	182	11 (6.0)	N.A.	0.52 (0.18, 1.51) 0.2231	0.2319
SEX								
MALE	269	13 (4.8)	N.A.	269	20 (7.4)	N.A.	0.69 (0.34, 1.39) 0.2933	
FEMALE	63	7 (11.1)	N.A.	56	4 (7.1)	N.A.	1.68 (0.49, 5.79) 0.4015	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4537
HBV	98	5 (5.1)	N.A.	95	4 (4.2)	N.A.	1.44 (0.39, 5.37) 0.5863	
HCV	27	1 (3.7)	N.A.	25	4 (16.0)	N.A.	0.29 (0.03, 2.63) 0.2441	
UNINFECTED	207	14 (6.8)	N.A.	205	16 (7.8)	N.A.	0.88 (0.43, 1.82) 0.7367	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Myalgia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4178
PRESENT	204	14 (6.9)	N.A.	199	14 (7.0)	N.A.	1.11 (0.53, 2.32) 0.7906	
ABSENT	128	6 (4.7)	N.A.	126	10 (7.9)	N.A.	0.57 (0.21, 1.58) 0.2772	
BASELINE ALPHA-- FETOPROTEIN								0.9464
< 400 NG/ML	224	15 (6.7)	N.A.	217	18 (8.3)	N.A.	0.85 (0.43, 1.68) 0.6355	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	6 (5.6)	N.A.	0.90 (0.27, 2.97) 0.8617	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Pain In Extremity

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	14 (4.2)	N.A.	325	13 (4.0)	N.A.	1.17 (0.55, 2.49) 0.6908	0.2957
AGE < 65	162	7 (4.3)	N.A.	143	3 (2.1)	N.A.	2.08 (0.53, 8.09) 0.2817	
>= 65	170	7 (4.1)	N.A.	182	10 (5.5)	N.A.	0.93 (0.35, 2.43) 0.8742	
SEX								0.6037
MALE	269	9 (3.3)	N.A.	269	10 (3.7)	N.A.	0.97 (0.39, 2.41) 0.9553	
FEMALE	63	5 (7.9)	N.A.	56	3 (5.4)	N.A.	1.68 (0.40, 7.05) 0.4706	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Pain In Extremity

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8657
HBV	98	3 (3.1)	N.A.	95	2 (2.1)	N.A.	1.49 (0.24, 9.07) 0.6638	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E. 0.2207	
UNINFECTED	207	10 (4.8)	N.A.	205	11 (5.4)	N.A.	1.00 (0.43, 2.37) 0.9945	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Pain In Extremity

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4476
PRESENT	204	8 (3.9)	N.A.	199	9 (4.5)	N.A.	0.95 (0.36, 2.46) 0.9105	
ABSENT	128	6 (4.7)	N.A.	126	4 (3.2)	N.A.	1.69 (0.47, 6.02) 0.4133	
BASELINE ALPHA-- FETOPROTEIN								0.2581
< 400 NG/ML	224	13 (5.8)	N.A.	217	10 (4.6)	N.A.	1.41 (0.62, 3.22) 0.4159	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	3 (2.8)	N.A.	0.38 (0.04, 3.67) 0.3835	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Muscle Spasms

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	10 (3.1)	N.A.	1.40 (0.61, 3.25) 0.4269	0.5710
AGE								
< 65	162	6 (3.7)	N.A.	143	3 (2.1)	N.A.	1.96 (0.49, 7.83) 0.3337	
>= 65	170	6 (3.5)	N.A.	182	7 (3.8)	N.A.	1.17 (0.39, 3.49) 0.7740	0.7440
SEX								
MALE	269	10 (3.7)	N.A.	269	9 (3.3)	N.A.	1.34 (0.54, 3.29) 0.5278	
FEMALE	63	2 (3.2)	N.A.	56	1 (1.8)	N.A.	1.98 (0.18, 21.83) 0.5700	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Muscle Spasms

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8377
HBV	98	1 (1.0)	N.A.	95	2 (2.1)	N.A.	0.60 (0.05, 6.57) 0.6688	
HCV	27	2 (7.4)	N.A. (9.20, N.A.)	25	0	N.E.	N.E. 0.0962	
UNINFECTED	207	9 (4.3)	N.A.	205	8 (3.9)	N.A.	1.30 (0.50, 3.38) 0.5831	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Muscle Spasms

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8252
PRESENT	204	8 (3.9)	N.A.	199	7 (3.5)	N.A.	1.31 (0.47, 3.62) 0.6018	
ABSENT	128	4 (3.1)	N.A.	126	3 (2.4)	N.A.	1.61 (0.36, 7.21) 0.5276	
BASELINE ALPHA-- FETOPROTEIN								0.4708
< 400 NG/ML	224	8 (3.6)	N.A.	217	8 (3.7)	N.A.	1.17 (0.44, 3.11) 0.7567	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	2 (1.9)	N.A.	2.57 (0.47, 14.07) 0.2581	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Musculoskeletal Chest Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	1 (0.3)	N.A.	325	11 (3.4)	44.81 (N.A., N.A.)	0.10 (0.01, 0.77) 0.0069	
AGE								N.M.E.
< 65	162	1 (0.6)	N.M.E.	143	4 (2.8)	N.M.E.	N.M.E.	
>= 65	170	0	N.E.	182	7 (3.8)	N.M.E.	N.E.	
SEX								0.9925
MALE	269	1 (0.4)	N.A.	269	10 (3.7)	44.81 (N.A., N.A.)	0.11 (0.01, 0.89) 0.0135	
FEMALE	63	0	N.E.	56	1 (1.8)	N.A.	N.E. 0.3088	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Musculoskeletal Chest Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	1 (1.0)	N.M.E.	95	1 (1.1)	N.M.E.	N.M.E.	
HCV	27	0	N.E.	25	1 (4.0)	N.M.E.	N.E.	
UNINFECTED	207	0	N.E.	205	9 (4.4)	N.M.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders. PT: Musculoskeletal Chest Pain

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	1 (0.5)	N.M.E.	199	7 (3.5)	N.M.E.	N.M.E.	
ABSENT	128	0	N.E.	126	4 (3.2)	N.M.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								0.9944
< 400 NG/ML	224	1 (0.4)	N.A.	217	10 (4.6)	44.81 (N.A., N.A.)	0.11 (0.01, 0.87) 0.0118	
>= 400 NG/ML	108	0	N.E.	108	1 (0.9)	N.A.	N.E. 0.3553	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	101 (30.4)	24.57 (11.47, N.A.)	325	105 (32.3)	N.A. (19.15, N.A.)	1.06 (0.80, 1.39) 0.6755	0.1512
AGE < 65	162	56 (34.6)	N.A. (5.88, N.A.)	143	42 (29.4)	19.15 (16.36, N.A.)	1.30 (0.87, 1.94) 0.1994	
>= 65	170	45 (26.5)	24.57 (N.A., N.A.)	182	63 (34.6)	N.A. (12.81, N.A.)	0.87 (0.60, 1.28) 0.4996	
SEX								0.0977
MALE	269	75 (27.9)	N.A.	269	75 (27.9)	N.A. (19.15, N.A.)	1.14 (0.83, 1.58) 0.4073	
FEMALE	63	26 (41.3)	3.91 (3.48, N.A.)	56	30 (53.6)	2.76 (2.07, 12.81)	0.66 (0.39, 1.13) 0.1337	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9302
HBV	98	28 (28.6)	N.A. (3.71, N.A.)	95	32 (33.7)	19.15 (9.20, N.A.)	0.95 (0.57, 1.59) 0.8549	
HCV	27	6 (22.2)	N.A. (4.86, N.A.)	25	6 (24.0)	N.A. (7.33, N.A.)	1.20 (0.39, 3.74) 0.7345	
UNINFECTED	207	67 (32.4)	24.57 (6.47, N.A.)	205	67 (32.7)	N.A.	1.11 (0.79, 1.56) 0.5362	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5888
PRESENT	204	59 (28.9)	N.A. (8.28, N.A.)	199	65 (32.7)	21.72 (9.69, N.A.)	0.99 (0.70, 1.41) 0.9639	
ABSENT	128	42 (32.8)	24.57 (5.95, N.A.)	126	40 (31.7)	N.A. (19.15, N.A.)	1.16 (0.75, 1.80) 0.4926	
BASELINE ALPHA-- FETOPROTEIN								0.2962
< 400 NG/ML	224	70 (31.3)	24.57 (7.13, N.A.)	217	66 (30.4)	N.A. (19.15, N.A.)	1.18 (0.84, 1.65) 0.3391	
>= 400 NG/ML	108	31 (28.7)	N.A. (4.07, N.A.)	108	39 (36.1)	21.72 (4.63, N.A.)	0.84 (0.52, 1.35) 0.4804	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Hypothyroidism

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	49 (14.8)	N.A.	325	88 (27.1)	N.A. (21.72, N.A.)	0.57 (0.40, 0.80) 0.0013	0.1747
AGE < 65	162	28 (17.3)	N.A.	143	35 (24.5)	N.A. (19.15, N.A.)	0.72 (0.44, 1.18) 0.1943	
>= 65	170	21 (12.4)	N.A.	182	53 (29.1)	N.A. (21.72, N.A.)	0.45 (0.27, 0.75) 0.0015	
SEX								0.1533
MALE	269	35 (13.0)	N.A.	269	60 (22.3)	N.A.	0.63 (0.41, 0.95) 0.0282	
FEMALE	63	14 (22.2)	N.A. (6.37, N.A.)	56	28 (50.0)	2.79 (2.10, N.A.)	0.36 (0.19, 0.69) 0.0012	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Hypothyroidism

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3546
HBV	98	8 (8.2)	N.A.	95	24 (25.3)	N.A. (19.15, N.A.)	0.32 (0.14, 0.72) 0.0037	
HCV	27	3 (11.1)	N.A. (11.47, N.A.)	25	4 (16.0)	N.A.	0.91 (0.20, 4.08) 0.9065	
UNINFECTED	207	38 (18.4)	N.A.	205	60 (29.3)	N.A.	0.65 (0.43, 0.97) 0.0348	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Hypothyroidism

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8227
PRESENT	204	30 (14.7)	N.A.	199	52 (26.1)	N.A. (21.72, N.A.)	0.58 (0.37, 0.91) 0.0173	
ABSENT	128	19 (14.8)	N.A.	126	36 (28.6)	N.A. (19.15, N.A.)	0.54 (0.31, 0.94) 0.0275	
BASELINE ALPHA-- FETOPROTEIN								0.9993
< 400 NG/ML	224	31 (13.8)	N.A.	217	55 (25.3)	N.A.	0.57 (0.37, 0.89) 0.0121	
>= 400 NG/ML	108	18 (16.7)	N.A.	108	33 (30.6)	21.72 (9.69, N.A.)	0.55 (0.31, 0.98) 0.0425	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Hyperthyroidism

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	37 (11.1)	N.A.	325	5 (1.5)	N.A.	8.89 (3.49, 22.62) <0.0001	0.6510
AGE								
< 65	162	21 (13.0)	N.A.	143	3 (2.1)	N.A.	7.29 (2.17, 24.45) 0.0002	
>= 65	170	16 (9.4)	N.A.	182	2 (1.1)	N.A.	10.87 (2.50, 47.31) <0.0001	0.7516
SEX								
MALE	269	26 (9.7)	N.A.	269	4 (1.5)	N.A.	7.93 (2.76, 22.73) <0.0001	
FEMALE	63	11 (17.5)	N.A.	56	1 (1.8)	N.A.	11.89 (1.53, 92.11) 0.0025	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Hyperthyroidism

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3177
HBV	98	12 (12.2)	N.A.	95	1 (1.1)	N.A.	14.99 (1.95, >99.99) 0.0005	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A.	1.07 (0.07, 17.15) 0.9606	
UNINFECTED	207	24 (11.6)	N.A.	205	3 (1.5)	N.A.	9.56 (2.88, 31.77) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Hyperthyroidism

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2854
PRESENT	204	20 (9.8)	N.A.	199	4 (2.0)	N.A.	5.90 (2.02, 17.28) 0.0002	
ABSENT	128	17 (13.3)	N.A.	126	1 (0.8)	N.A.	20.79 (2.77, >99.99) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.9851
< 400 NG/ML	224	23 (10.3)	N.A.	217	3 (1.4)	N.A.	8.88 (2.66, 29.60) <0.0001	
>= 400 NG/ML	108	14 (13.0)	N.A.	108	2 (1.9)	N.A.	8.97 (2.04, 39.54) 0.0004	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	18 (5.4)	24.57 (N.A., N.A.)	325	0	N.E.	N.E. <0.0001	0.9999
AGE								
< 65	162	11 (6.8)	N.A.	143	0	N.E.	N.E. 0.0007	
>= 65	170	7 (4.1)	24.57 (N.A., N.A.)	182	0	N.E.	N.E. 0.0003	0.9998
SEX								
MALE	269	11 (4.1)	N.A.	269	0	N.E.	N.E. 0.0002	
FEMALE	63	7 (11.1)	24.57 (N.A., N.A.)	56	0	N.E.	N.E. 0.0027	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	3 (3.1)	N.A.	95	0	N.E.	N.E. 0.0492	
HCV	27	2 (7.4)	N.A. (13.44, N.A.)	25	0	N.E.	N.E. 0.0935	
UNINFECTED	207	13 (6.3)	24.57 (N.A., N.A.)	205	0	N.E.	N.E. <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Adrenal Insufficiency

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								>0.9999
PRESENT	204	11 (5.4)	N.A.	199	0	N.E.	N.E. 0.0003	
ABSENT	128	7 (5.5)	24.57 (N.A., N.A.)	126	0	N.E.	N.E. 0.0007	
BASELINE ALPHA-- FETOPROTEIN								>0.9999
< 400 NG/ML	224	13 (5.8)	24.57 (N.A., N.A.)	217	0	N.E.	N.E. <0.0001	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	0	N.E.	N.E. 0.0264	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Thyroiditis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	16 (4.8)	N.A.	325	14 (4.3)	N.A.	1.31 (0.64, 2.69) 0.4597	0.4768
AGE < 65	162	10 (6.2)	N.A.	143	6 (4.2)	N.A.	1.65 (0.60, 4.53) 0.3304	
>= 65	170	6 (3.5)	N.A.	182	8 (4.4)	N.A.	1.00 (0.35, 2.89) 0.9950	
SEX								0.8835
MALE	269	13 (4.8)	N.A.	269	12 (4.5)	N.A.	1.28 (0.59, 2.82) 0.5312	
FEMALE	63	3 (4.8)	N.A.	56	2 (3.6)	N.A.	1.49 (0.25, 8.94) 0.6581	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects
SOC: Endocrine Disorders. PT: Thyroiditis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9285
HBV	98	9 (9.2)	N.A.	95	7 (7.4)	N.A.	1.52 (0.56, 4.07) 0.4080	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A.	1.25 (0.08, 20.23) 0.8744	
UNINFECTED	207	6 (2.9)	N.A.	205	6 (2.9)	N.A.	1.17 (0.38, 3.63) 0.7855	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders. PT: Thyroiditis

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5660
PRESENT	204	10 (4.9)	N.A.	199	10 (5.0)	N.A.	1.10 (0.46, 2.65) 0.8319	
ABSENT	128	6 (4.7)	N.A.	126	4 (3.2)	N.A.	1.81 (0.51, 6.43) 0.3496	
BASELINE ALPHA-- FETOPROTEIN								0.3345
< 400 NG/ML	224	13 (5.8)	N.A.	217	9 (4.1)	N.A.	1.60 (0.68, 3.75) 0.2721	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	5 (4.6)	N.A.	0.77 (0.18, 3.24) 0.7232	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	83 (25.0)	N.A. (20.57, N.A.)	325	71 (21.8)	N.A.	1.35 (0.98, 1.85) 0.0660	0.9050
AGE < 65	162	41 (25.3)	N.A. (14.82, N.A.)	143	29 (20.3)	N.A. (25.03, N.A.)	1.42 (0.88, 2.30) 0.1523	
>= 65	170	42 (24.7)	N.A. (13.34, N.A.)	182	42 (23.1)	N.A. (18.56, N.A.)	1.31 (0.86, 2.02) 0.2110	
SEX								0.9170
MALE	269	68 (25.3)	N.A. (18.10, N.A.)	269	59 (21.9)	N.A.	1.32 (0.93, 1.88) 0.1166	
FEMALE	63	15 (23.8)	N.A. (6.44, N.A.)	56	12 (21.4)	N.A. (25.03, N.A.)	1.38 (0.63, 3.00) 0.4225	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects
SOC: Blood and Lymphatic System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6448
HBV	98	20 (20.4)	N.A. (14.49, N.A.)	95	17 (17.9)	N.A. (25.03, N.A.)	1.36 (0.70, 2.63) 0.3535	
HCV	27	5 (18.5)	N.A. (9.43, N.A.)	25	7 (28.0)	N.A. (6.64, N.A.)	0.83 (0.26, 2.64) 0.7556	
UNINFECTED	207	58 (28.0)	N.A. (10.81, N.A.)	205	47 (22.9)	N.A. (18.56, N.A.)	1.42 (0.96, 2.09) 0.0757	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5877
PRESENT	204	51 (25.0)	N.A. (13.34, N.A.)	199	40 (20.1)	N.A. (25.03, N.A.)	1.47 (0.97, 2.24) 0.0670	
ABSENT	128	32 (25.0)	N.A. (14.49, N.A.)	126	31 (24.6)	N.A. (18.56, N.A.)	1.19 (0.73, 1.95) 0.4917	
BASELINE ALPHA-- FETOPROTEIN								0.9026
< 400 NG/ML	224	61 (27.2)	N.A. (14.49, N.A.)	217	51 (23.5)	N.A.	1.34 (0.92, 1.95) 0.1229	
>= 400 NG/ML	108	22 (20.4)	N.A. (18.10, N.A.)	108	20 (18.5)	N.A. (25.03, N.A.)	1.35 (0.73, 2.51) 0.3364	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	46 (13.9)	N.A.	325	29 (8.9)	N.A.	1.93 (1.20, 3.09) 0.0054	0.2643
AGE								
< 65	162	22 (13.6)	N.A.	143	15 (10.5)	N.A.	1.52 (0.78, 2.97) 0.2195	
>= 65	170	24 (14.1)	N.A.	182	14 (7.7)	N.A.	2.37 (1.23, 4.60) 0.0083	0.5159
SEX								
MALE	269	37 (13.8)	N.A.	269	22 (8.2)	N.A.	1.98 (1.17, 3.37) 0.0097	
FEMALE	63	9 (14.3)	N.A.	56	7 (12.5)	N.A. (25.03, N.A.)	1.60 (0.57, 4.50) 0.3690	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8205
HBV	98	8 (8.2)	N.A.	95	4 (4.2)	N.A. (25.03, N.A.)	3.17 (0.84, 11.96) 0.0725	
HCV	27	4 (14.8)	N.A. (9.43, N.A.)	25	2 (8.0)	N.A. (16.36, N.A.)	2.50 (0.45, 13.79) 0.2761	
UNINFECTED	207	34 (16.4)	N.A.	205	23 (11.2)	N.A.	1.71 (1.01, 2.91) 0.0448	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3493
PRESENT	204	29 (14.2)	N.A.	199	15 (7.5)	N.A.	2.40 (1.27, 4.55) 0.0056	
ABSENT	128	17 (13.3)	N.A.	126	14 (11.1)	N.A.	1.47 (0.73, 2.99) 0.2822	
BASELINE ALPHA-- FETOPROTEIN								0.3730
< 400 NG/ML	224	33 (14.7)	N.A.	217	18 (8.3)	N.A.	2.14 (1.21, 3.81) 0.0078	
>= 400 NG/ML	108	13 (12.0)	N.A.	108	11 (10.2)	N.A. (17.35, N.A.)	1.49 (0.65, 3.41) 0.3470	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	22 (6.6)	N.A.	325	38 (11.7)	N.A.	0.61 (0.36, 1.03) 0.0610	0.0270*
AGE								
< 65	162	14 (8.6)	N.A.	143	11 (7.7)	N.A.	1.22 (0.55, 2.69) 0.6179	
>= 65	170	8 (4.7)	N.A.	182	27 (14.8)	N.A.	0.33 (0.15, 0.74) 0.0045	0.6251
SEX								
MALE	269	17 (6.3)	N.A.	269	32 (11.9)	N.A.	0.56 (0.31, 1.01) 0.0518	
FEMALE	63	5 (7.9)	N.A.	56	6 (10.7)	N.A.	0.83 (0.25, 2.71) 0.7481	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8441
HBV	98	5 (5.1)	N.A.	95	10 (10.5)	N.A.	0.53 (0.18, 1.54) 0.2368	
HCV	27	3 (11.1)	N.A.	25	4 (16.0)	N.A.	0.95 (0.21, 4.28) 0.9498	
UNINFECTED	207	14 (6.8)	N.A.	205	24 (11.7)	N.A.	0.58 (0.29, 1.12) 0.1005	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Thrombocytopenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2125
PRESENT	204	10 (4.9)	N.A.	199	23 (11.6)	N.A.	0.42 (0.20, 0.90) 0.0214	
ABSENT	128	12 (9.4)	N.A.	126	15 (11.9)	N.A.	0.90 (0.42, 1.92) 0.7793	
BASELINE ALPHA-- FETOPROTEIN								0.3313
< 400 NG/ML	224	18 (8.0)	N.A.	217	27 (12.4)	N.A.	0.71 (0.39, 1.30) 0.2648	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	11 (10.2)	N.A.	0.36 (0.11, 1.14) 0.0704	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	21 (6.3)	N.A.	325	17 (5.2)	N.A. (34.27, N.A.)	1.48 (0.77, 2.83) 0.2388	0.2056
AGE < 65	162	10 (6.2)	N.A.	143	10 (7.0)	N.A.	0.94 (0.39, 2.26) 0.8899	
>= 65	170	11 (6.5)	N.A.	182	7 (3.8)	N.A. (34.27, N.A.)	2.43 (0.90, 6.61) 0.0719	
SEX								0.2906
MALE	269	15 (5.6)	N.A.	269	15 (5.6)	N.A. (34.27, N.A.)	1.19 (0.57, 2.48) 0.6347	
FEMALE	63	6 (9.5)	N.A.	56	2 (3.6)	N.A.	3.23 (0.65, 16.01) 0.1289	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9251
HBV	98	4 (4.1)	N.A.	95	3 (3.2)	N.A.	1.47 (0.33, 6.61) 0.6096	
HCV	27	3 (11.1)	N.A. (9.43, N.A.)	25	2 (8.0)	N.A.	1.85 (0.31, 11.14) 0.4938	
UNINFECTED	207	14 (6.8)	N.A.	205	12 (5.9)	N.A. (34.27, N.A.)	1.41 (0.64, 3.11) 0.3966	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Neutropenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8729
PRESENT	204	11 (5.4)	N.A.	199	9 (4.5)	N.A.	1.36 (0.56, 3.28) 0.4961	
ABSENT	128	10 (7.8)	N.A.	126	8 (6.3)	34.27 (34.27, N.A.)	1.63 (0.62, 4.30) 0.3166	
BASELINE ALPHA-- FETOPROTEIN								0.3079
< 400 NG/ML	224	16 (7.1)	N.A.	217	15 (6.9)	N.A. (34.27, N.A.)	1.26 (0.61, 2.59) 0.5261	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	2 (1.9)	N.A.	3.19 (0.62, 16.48) 0.1443	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Eosinophilia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	2 (0.6)	N.A.	6.20 (1.38, 27.91) 0.0067	
AGE								N.M.E.
< 65	162	7 (4.3)	N.M.E.	143	1 (0.7)	N.M.E.	N.M.E.	
>= 65	170	5 (2.9)	N.M.E.	182	1 (0.5)	N.M.E.	N.M.E.	
SEX								0.9911
MALE	269	10 (3.7)	N.A.	269	2 (0.7)	N.A.	5.27 (1.14, 24.28) 0.0176	
FEMALE	63	2 (3.2)	N.A.	56	0	N.E.	N.E. 0.1553	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Eosinophilia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	6 (6.1)	N.M.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	1 (4.0)	N.M.E.	N.E.	
UNINFECTED	207	6 (2.9)	N.M.E.	205	1 (0.5)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Eosinophilia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	6 (2.9)	N.M.E.	199	2 (1.0)	N.M.E.	N.M.E.	
ABSENT	128	6 (4.7)	N.M.E.	126	0	N.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								N.M.E.
< 400 NG/ML	224	8 (3.6)	N.M.E.	217	1 (0.5)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	4 (3.7)	N.M.E.	108	1 (0.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	N.A.	325	9 (2.8)	N.A.	1.11 (0.45, 2.76) 0.8178	0.6009
AGE < 65	162	4 (2.5)	N.A.	143	4 (2.8)	N.A.	0.93 (0.23, 3.72) 0.9167	
>= 65	170	6 (3.5)	N.A.	182	5 (2.7)	N.A.	1.28 (0.38, 4.31) 0.6845	
SEX								0.3748
MALE	269	7 (2.6)	N.A.	269	8 (3.0)	N.A.	0.84 (0.30, 2.36) 0.7451	
FEMALE	63	3 (4.8)	N.A.	56	1 (1.8)	N.A.	3.06 (0.32, 29.45) 0.3077	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9937
HBV	98	1 (1.0)	N.A.	95	0	N.E.	N.E. 0.3308	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A.	1.04 (0.07, 16.70) 0.9755	
UNINFECTED	207	8 (3.9)	N.A.	205	8 (3.9)	N.A.	0.92 (0.34, 2.51) 0.8776	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Leukopenia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7648
PRESENT	204	4 (2.0)	N.A.	199	4 (2.0)	N.A.	1.01 (0.25, 4.09) 0.9841	
ABSENT	128	6 (4.7)	N.A.	126	5 (4.0)	N.A.	1.22 (0.37, 4.04) 0.7454	
BASELINE ALPHA-- FETOPROTEIN								0.4227
< 400 NG/ML	224	9 (4.0)	N.A.	217	7 (3.2)	N.A.	1.30 (0.48, 3.52) 0.6005	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	2 (1.9)	N.A.	0.53 (0.05, 5.87) 0.5993	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	83 (25.0)	25.26 (N.A., N.A.)	325	92 (28.3)	22.51 (16.59, N.A.)	0.95 (0.71, 1.29) 0.7575	0.7573
AGE								
< 65	162	39 (24.1)	N.A.	143	37 (25.9)	22.51 (16.59, N.A.)	0.99 (0.63, 1.55) 0.9512	
>= 65	170	44 (25.9)	25.26 (22.60, N.A.)	182	55 (30.2)	N.A. (11.76, N.A.)	0.94 (0.63, 1.41) 0.7778	0.8021
SEX								
MALE	269	63 (23.4)	25.26 (N.A., N.A.)	269	71 (26.4)	N.A. (17.51, N.A.)	0.97 (0.69, 1.37) 0.8803	
FEMALE	63	20 (31.7)	N.A. (4.57, N.A.)	56	21 (37.5)	16.59 (8.25, 22.51)	0.84 (0.45, 1.55) 0.5694	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8361
HBV	98	18 (18.4)	N.A.	95	24 (25.3)	N.A. (18.86, N.A.)	0.83 (0.45, 1.53) 0.5459	
HCV	27	7 (25.9)	N.A. (6.08, N.A.)	25	7 (28.0)	14.92 (11.70, N.A.)	1.19 (0.42, 3.41) 0.7424	
UNINFECTED	207	58 (28.0)	25.26 (22.60, N.A.)	205	61 (29.8)	17.51 (10.18, N.A.)	0.98 (0.68, 1.40) 0.8950	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1979
PRESENT	204	53 (26.0)	25.26 (N.A., N.A.)	199	51 (25.6)	22.51 (17.51, N.A.)	1.16 (0.78, 1.70) 0.4653	
ABSENT	128	30 (23.4)	N.A. (22.60, N.A.)	126	41 (32.5)	N.A. (13.83, N.A.)	0.73 (0.46, 1.17) 0.1916	
BASELINE ALPHA-- FETOPROTEIN								0.8378
< 400 NG/ML	224	58 (25.9)	25.26 (N.A., N.A.)	217	63 (29.0)	N.A. (15.18, N.A.)	0.98 (0.68, 1.40) 0.8960	
>= 400 NG/ML	108	25 (23.1)	N.A.	108	29 (26.9)	16.59 (11.70, N.A.)	0.91 (0.53, 1.56) 0.7279	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Headache

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	29 (8.7)	N.A.	325	37 (11.4)	N.A.	0.80 (0.49, 1.31) 0.3706	0.0965
AGE								
< 65	162	21 (13.0)	N.A.	143	17 (11.9)	N.A.	1.10 (0.58, 2.09) 0.7767	
>= 65	170	8 (4.7)	N.A.	182	20 (11.0)	(22.51, N.A.) N.A.	0.47 (0.21, 1.07) 0.0657	0.5469
SEX								
MALE	269	21 (7.8)	N.A.	269	26 (9.7)	N.A.	0.86 (0.48, 1.54) 0.6128	
FEMALE	63	8 (12.7)	N.A.	56	11 (19.6)	22.51 (22.51, N.A.)	0.60 (0.24, 1.51) 0.2730	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Headache

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1940
HBV	98	10 (10.2)	N.A.	95	12 (12.6)	N.A. (22.51, N.A.)	0.85 (0.36, 1.98) 0.7064	
HCV	27	5 (18.5)	N.A. (12.09, N.A.)	25	2 (8.0)	21.59 (21.59, N.A.)	3.05 (0.59, 15.78) 0.1625	
UNINFECTED	207	14 (6.8)	N.A.	205	23 (11.2)	N.A.	0.65 (0.33, 1.26) 0.1958	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Headache

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2463
PRESENT	204	20 (9.8)	N.A.	199	20 (10.1)	N.A.	1.02 (0.55, 1.92) 0.9415	
ABSENT	128	9 (7.0)	N.A.	126	17 (13.5)	N.A.	0.55 (0.24, 1.23) 0.1371	
BASELINE ALPHA-- FETOPROTEIN								0.5934
< 400 NG/ML	224	22 (9.8)	N.A.	217	26 (12.0)	N.A.	0.89 (0.50, 1.58) 0.6892	
>= 400 NG/ML	108	7 (6.5)	N.A.	108	11 (10.2)	N.A. (22.51, N.A.)	0.60 (0.23, 1.58) 0.2968	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Dizziness

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	24.77 (N.A., N.A.)	325	15 (4.6)	42.81 (N.A., N.A.)	1.00 (0.46, 2.19) 0.9956	0.9706
AGE < 65	162	6 (3.7)	N.A.	143	6 (4.2)	N.A.	0.89 (0.29, 2.78) 0.8470	
>= 65	170	6 (3.5)	24.77 (N.A., N.A.)	182	9 (4.9)	42.81 (N.A., N.A.)	1.09 (0.37, 3.21) 0.8797	
SEX								0.5631
MALE	269	9 (3.3)	24.77 (N.A., N.A.)	269	13 (4.8)	42.81 (N.A., N.A.)	0.90 (0.37, 2.16) 0.8080	
FEMALE	63	3 (4.8)	N.A.	56	2 (3.6)	N.A.	1.50 (0.25, 8.96) 0.6562	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Dizziness

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1369
HBV	98	5 (5.1)	N.A.	95	1 (1.1)	N.A.	5.74 (0.67, 49.16) 0.0713	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A.	1.27 (0.08, 20.36) 0.8640	
UNINFECTED	207	6 (2.9)	24.77 (N.A., N.A.)	205	13 (6.3)	42.81 (N.A., N.A.)	0.57 (0.21, 1.55) 0.2657	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Dizziness

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9493
PRESENT	204	6 (2.9)	N.A.	199	7 (3.5)	N.A.	0.95 (0.32, 2.84) 0.9298	
ABSENT	128	6 (4.7)	24.77 (N.A., N.A.)	126	8 (6.3)	42.81 (N.A., N.A.)	1.04 (0.34, 3.19) 0.9437	
BASELINE ALPHA-- FETOPROTEIN								0.8156
< 400 NG/ML	224	9 (4.0)	24.77 (N.A., N.A.)	217	11 (5.1)	42.81 (N.A., N.A.)	1.09 (0.43, 2.73) 0.8576	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	4 (3.7)	N.A.	0.84 (0.19, 3.77) 0.8196	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Hepatic Encephalopathy

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	25.26 (N.A., N.A.)	325	13 (4.0)	N.A.	0.87 (0.37, 2.02) 0.7399	0.9906
AGE								
< 65	162	0	N.E.	143	6 (4.2)	N.A.	N.E. 0.0053	
>= 65	170	10 (5.9)	25.26 (N.A., N.A.)	182	7 (3.8)	N.A.	2.08 (0.77, 5.65) 0.1406	0.9909
SEX								
MALE	269	10 (3.7)	25.26 (N.A., N.A.)	269	11 (4.1)	N.A.	1.10 (0.46, 2.64) 0.8372	
FEMALE	63	0	N.E.	56	2 (3.6)	N.A. (18.86, N.A.)	N.E. 0.1015	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Hepatic Encephalopathy

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	0	N.E.	95	1 (1.1)	N.A.	N.E. 0.2440	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	10 (4.8)	25.26 (N.A., N.A.)	205	12 (5.9)	N.A.	0.94 (0.40, 2.22) 0.8849	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders. PT: Hepatic Encephalopathy

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9518
PRESENT	204	8 (3.9)	25.26 (N.A., N.A.)	199	10 (5.0)	N.A.	0.88 (0.34, 2.29) 0.7897	
ABSENT	128	2 (1.6)	N.A.	126	3 (2.4)	N.A.	0.73 (0.12, 4.41) 0.7296	
BASELINE ALPHA-- FETOPROTEIN								0.1502
< 400 NG/ML	224	9 (4.0)	25.26 (N.A., N.A.)	217	8 (3.7)	N.A.	1.29 (0.48, 3.45) 0.6110	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	5 (4.6)	N.A.	0.23 (0.03, 2.01) 0.1488	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva		Test for Interaction P-value (4)(5)
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)		
OVERALL	332	70 (21.1)	N.A.	325	44 (13.5)	N.A. (36.93, N.A.)	1.79 (1.22, 2.62) 0.0025		
AGE									0.3513
< 65	162	29 (17.9)	N.A.	143	19 (13.3)	N.A. (36.93, N.A.)	1.53 (0.85, 2.76) 0.1553		
>= 65	170	41 (24.1)	N.A.	182	25 (13.7)	N.A.	2.06 (1.25, 3.40) 0.0038		
SEX									0.2542
MALE	269	60 (22.3)	N.A.	269	35 (13.0)	N.A. (36.93, N.A.)	1.98 (1.30, 3.02) 0.0013		
FEMALE	63	10 (15.9)	N.A.	56	9 (16.1)	N.A. (17.51, N.A.)	1.10 (0.45, 2.71) 0.8337		

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9699
HBV	98	14 (14.3)	N.A.	95	10 (10.5)	36.93 (N.A., N.A.)	1.72 (0.74, 3.98) 0.2028	
HCV	27	6 (22.2)	N.A.	25	4 (16.0)	N.A. (17.51, N.A.)	1.59 (0.45, 5.65) 0.4705	
UNINFECTED	207	50 (24.2)	N.A.	205	30 (14.6)	N.A.	1.79 (1.13, 2.82) 0.0113	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5234
PRESENT	204	47 (23.0)	N.A.	199	26 (13.1)	36.93 (36.93, N.A.)	2.02 (1.24, 3.29) 0.0037	
ABSENT	128	23 (18.0)	N.A.	126	18 (14.3)	N.A.	1.44 (0.77, 2.68) 0.2507	
BASELINE ALPHA-- FETOPROTEIN								0.7024
< 400 NG/ML	224	42 (18.8)	N.A.	217	28 (12.9)	N.A. (36.93, N.A.)	1.70 (1.05, 2.76) 0.0300	
>= 400 NG/ML	108	28 (25.9)	N.A.	108	16 (14.8)	N.A. (14.69, N.A.)	1.98 (1.07, 3.69) 0.0271	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders. PT: Hyperbilirubinaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	11 (3.4)	N.A.	1.25 (0.56, 2.80) 0.5912	0.1297
AGE < 65	162	4 (2.5)	N.A.	143	6 (4.2)	N.A.	0.63 (0.18, 2.23) 0.4686	
>= 65	170	9 (5.3)	N.A.	182	5 (2.7)	N.A.	2.14 (0.71, 6.44) 0.1652	
SEX								0.9902
MALE	269	13 (4.8)	N.A.	269	9 (3.3)	N.A.	1.56 (0.66, 3.66) 0.3078	
FEMALE	63	0	N.E.	56	2 (3.6)	N.A.	N.E. 0.1536	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders. PT: Hyperbilirubinaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7722
HBV	98	2 (2.0)	N.A.	95	3 (3.2)	N.A.	0.74 (0.12, 4.45) 0.7428	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A.	0.96 (0.06, 15.32) 0.9755	
UNINFECTED	207	10 (4.8)	N.A.	205	7 (3.4)	N.A.	1.45 (0.55, 3.85) 0.4506	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders. PT: Hyperbilirubinaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4416
PRESENT	204	9 (4.4)	N.A.	199	9 (4.5)	N.A.	1.05 (0.42, 2.66) 0.9105	
ABSENT	128	4 (3.1)	N.A.	126	2 (1.6)	N.A.	2.08 (0.37, 11.58) 0.3934	
BASELINE ALPHA-- FETOPROTEIN								0.6051
< 400 NG/ML	224	7 (3.1)	N.A.	217	7 (3.2)	N.A.	1.01 (0.35, 2.91) 0.9824	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	4 (3.7)	N.A.	1.75 (0.49, 6.21) 0.3796	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	63 (19.0)	24.51 (N.A., N.A.)	325	86 (26.5)	26.97 (17.05, N.A.)	0.78 (0.56, 1.09) 0.1413	0.7399
AGE < 65	162	33 (20.4)	N.A.	143	41 (28.7)	18.23 (16.39, N.A.)	0.73 (0.46, 1.15) 0.1705	
>= 65	170	30 (17.6)	24.51 (N.A., N.A.)	182	45 (24.7)	26.97 (16.89, N.A.)	0.83 (0.52, 1.33) 0.4388	
SEX								0.9731
MALE	269	55 (20.4)	24.51 (N.A., N.A.)	269	76 (28.3)	18.23 (16.56, N.A.)	0.78 (0.55, 1.11) 0.1741	
FEMALE	63	8 (12.7)	N.A.	56	10 (17.9)	N.A.	0.79 (0.31, 2.03) 0.6272	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0296*
HBV	98	24 (24.5)	N.A. (17.31, N.A.)	95	23 (24.2)	N.A. (16.39, N.A.)	1.16 (0.65, 2.05) 0.6207	
HCV	27	6 (22.2)	N.A. (10.51, N.A.)	25	3 (12.0)	N.A. (14.72, N.A.)	2.28 (0.56, 9.24) 0.2370	
UNINFECTED	207	33 (15.9)	24.51 (N.A., N.A.)	205	60 (29.3)	18.14 (15.61, N.A.)	0.57 (0.37, 0.87) 0.0091	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3623
PRESENT	204	40 (19.6)	N.A.	199	59 (29.6)	18.14 (15.41, N.A.)	0.69 (0.46, 1.04) 0.0733	
ABSENT	128	23 (18.0)	24.51 (N.A., N.A.)	126	27 (21.4)	N.A. (17.05, N.A.)	0.98 (0.56, 1.72) 0.9424	
BASELINE ALPHA-- FETOPROTEIN								0.1633
< 400 NG/ML	224	40 (17.9)	24.51 (N.A., N.A.)	217	47 (21.7)	N.A. (18.23, N.A.)	0.90 (0.59, 1.38) 0.6315	
>= 400 NG/ML	108	23 (21.3)	N.A.	108	39 (36.1)	15.24 (8.94, 26.97)	0.65 (0.38, 1.09) 0.1027	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	52 (15.7)	24.51 (N.A., N.A.)	325	74 (22.8)	N.A. (18.07, N.A.)	0.76 (0.53, 1.09) 0.1297	0.9025
AGE < 65	162	28 (17.3)	N.A.	143	33 (23.1)	N.A. (17.58, N.A.)	0.76 (0.46, 1.26) 0.2896	
>= 65	170	24 (14.1)	24.51 (N.A., N.A.)	182	41 (22.5)	26.97 (16.89, N.A.)	0.75 (0.45, 1.25) 0.2648	
SEX								0.7775
MALE	269	44 (16.4)	24.51 (N.A., N.A.)	269	65 (24.2)	26.97 (17.05, N.A.)	0.75 (0.51, 1.11) 0.1489	
FEMALE	63	8 (12.7)	N.A. (20.93, N.A.)	56	9 (16.1)	N.A.	0.82 (0.31, 2.14) 0.6774	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0696
HBV	98	19 (19.4)	N.A. (20.93, N.A.)	95	19 (20.0)	N.A. (18.07, N.A.)	1.11 (0.58, 2.10) 0.7573	
HCV	27	5 (18.5)	N.A. (10.51, N.A.)	25	3 (12.0)	N.A. (14.72, N.A.)	2.10 (0.50, 8.80) 0.2989	
UNINFECTED	207	28 (13.5)	24.51 (N.A., N.A.)	205	52 (25.4)	26.97 (16.56, N.A.)	0.56 (0.35, 0.90) 0.0148	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5136
PRESENT	204	34 (16.7)	N.A.	199	51 (25.6)	26.97 (16.39, N.A.)	0.69 (0.44, 1.07) 0.0934	
ABSENT	128	18 (14.1)	24.51 (N.A., N.A.)	126	23 (18.3)	N.A. (20.24, N.A.)	0.91 (0.49, 1.70) 0.7702	
BASELINE ALPHA-- FETOPROTEIN								0.3599
< 400 NG/ML	224	30 (13.4)	24.51 (N.A., N.A.)	217	38 (17.5)	N.A.	0.83 (0.51, 1.35) 0.4568	
>= 400 NG/ML	108	22 (20.4)	N.A.	108	36 (33.3)	15.61 (9.43, N.A.)	0.68 (0.40, 1.17) 0.1581	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	56 (16.9)	N.A.	325	154 (47.4)	8.28 (2.14, N.A.)	0.28 (0.21, 0.38) <0.0001	0.0799
AGE								
< 65	162	20 (12.3)	N.A.	143	66 (46.2)	11.96 (2.14, N.A.)	0.21 (0.13, 0.34) <0.0001	
>= 65	170	36 (21.2)	N.A. (23.62, N.A.)	182	88 (48.4)	5.55 (2.00, N.A.)	0.35 (0.24, 0.52) <0.0001	0.7495
SEX								
MALE	269	42 (15.6)	N.A.	269	124 (46.1)	12.35 (2.76, N.A.)	0.27 (0.19, 0.38) <0.0001	
FEMALE	63	14 (22.2)	N.A.	56	30 (53.6)	2.10 (1.48, N.A.)	0.30 (0.16, 0.58) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4069
HBV	98	15 (15.3)	N.A.	95	51 (53.7)	2.14 (1.31, N.A.)	0.21 (0.12, 0.37) <0.0001	
HCV	27	5 (18.5)	N.A. (4.86, N.A.)	25	11 (44.0)	N.A. (0.69, N.A.)	0.39 (0.13, 1.12) 0.0692	
UNINFECTED	207	36 (17.4)	N.A.	205	92 (44.9)	12.35 (2.69, N.A.)	0.31 (0.21, 0.45) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3383
PRESENT	204	32 (15.7)	N.A.	199	96 (48.2)	5.55 (2.07, N.A.)	0.24 (0.16, 0.36) <0.0001	
ABSENT	128	24 (18.8)	N.A.	126	58 (46.0)	21.26 (2.04, N.A.)	0.34 (0.21, 0.55) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.1354
< 400 NG/ML	224	44 (19.6)	N.A.	217	103 (47.5)	12.35 (2.10, N.A.)	0.32 (0.23, 0.46) <0.0001	
>= 400 NG/ML	108	12 (11.1)	N.A.	108	51 (47.2)	6.67 (1.97, N.A.)	0.19 (0.10, 0.35) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypertension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	37 (11.1)	N.A.	325	145 (44.6)	12.48 (2.79, N.A.)	0.20 (0.14, 0.29) <0.0001	0.0949
AGE < 65	162	12 (7.4)	N.A.	143	60 (42.0)	16.59 (2.69, N.A.)	0.14 (0.08, 0.26) <0.0001	
>= 65	170	25 (14.7)	N.A.	182	85 (46.7)	12.35 (2.04, N.A.)	0.26 (0.17, 0.41) <0.0001	
SEX								0.6638
MALE	269	28 (10.4)	N.A.	269	118 (43.9)	16.59 (2.79, N.A.)	0.19 (0.13, 0.29) <0.0001	
FEMALE	63	9 (14.3)	N.A.	56	27 (48.2)	2.69 (1.54, N.A.)	0.24 (0.11, 0.50) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypertension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1938
HBV	98	8 (8.2)	N.A.	95	50 (52.6)	2.14 (1.35, N.A.)	0.12 (0.06, 0.25) <0.0001	
HCV	27	3 (11.1)	N.A.	25	10 (40.0)	N.A. (0.69, N.A.)	0.27 (0.07, 0.97) 0.0309	
UNINFECTED	207	26 (12.6)	N.A.	205	85 (41.5)	21.26 (8.28, N.A.)	0.25 (0.16, 0.38) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypertension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1066
PRESENT	204	18 (8.8)	N.A.	199	90 (45.2)	11.96 (2.14, N.A.)	0.15 (0.09, 0.25) <0.0001	
ABSENT	128	19 (14.8)	N.A.	126	55 (43.7)	21.26 (2.10, N.A.)	0.29 (0.17, 0.48) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.2975
< 400 NG/ML	224	28 (12.5)	N.A.	217	95 (43.8)	16.59 (2.17, N.A.)	0.23 (0.15, 0.35) <0.0001	
>= 400 NG/ML	108	9 (8.3)	N.A.	108	50 (46.3)	8.28 (2.07, N.A.)	0.15 (0.07, 0.31) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypotension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	5 (1.5)	N.A.	2.40 (0.83, 6.94) 0.0947	0.4670
AGE								
< 65	162	5 (3.1)	N.A.	143	1 (0.7)	N.A.	4.82 (0.56, 41.32) 0.1128	
>= 65	170	6 (3.5)	N.A.	182	4 (2.2)	N.A.	1.85 (0.52, 6.62) 0.3359	0.9892
SEX								
MALE	269	7 (2.6)	N.A.	269	5 (1.9)	N.A.	1.54 (0.48, 4.88) 0.4613	
FEMALE	63	4 (6.3)	N.A.	56	0	N.E.	N.E. 0.0486	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypotension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9065
HBV	98	3 (3.1)	N.A.	95	1 (1.1)	N.A.	3.43 (0.36, 33.05) 0.2561	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E. 0.2781	
UNINFECTED	207	7 (3.4)	N.A.	205	4 (2.0)	N.A.	1.86 (0.54, 6.39) 0.3194	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypotension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9891
PRESENT	204	8 (3.9)	N.A.	199	5 (2.5)	N.A.	1.66 (0.54, 5.10) 0.3744	
ABSENT	128	3 (2.3)	N.A.	126	0	N.E.	N.E. 0.0629	
BASELINE ALPHA-- FETOPROTEIN								0.1729
< 400 NG/ML	224	10 (4.5)	N.A.	217	3 (1.4)	N.A.	3.63 (0.99, 13.21) 0.0369	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	2 (1.9)	N.A.	0.55 (0.05, 6.06) 0.6167	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	38 (11.4)	N.A.	325	96 (29.5)	30.16 (15.67, N.A.)	0.37 (0.25, 0.54) <0.0001	0.0680
AGE								
< 65	162	13 (8.0)	N.A.	143	41 (28.7)	16.43 (14.55, N.A.)	0.24 (0.13, 0.45) <0.0001	
>= 65	170	25 (14.7)	N.A.	182	55 (30.2)	30.16 (13.93, N.A.)	0.51 (0.32, 0.82) 0.0050	0.9659
SEX								
MALE	269	32 (11.9)	N.A.	269	83 (30.9)	16.43 (14.55, N.A.)	0.36 (0.24, 0.55) <0.0001	
FEMALE	63	6 (9.5)	N.A.	56	13 (23.2)	N.A. (13.93, N.A.)	0.39 (0.15, 1.02) 0.0473	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4148
HBV	98	8 (8.2)	N.A.	95	29 (30.5)	N.A. (11.04, N.A.)	0.25 (0.11, 0.55) 0.0002	
HCV	27	3 (11.1)	N.A. (7.26, N.A.)	25	10 (40.0)	15.67 (10.15, N.A.)	0.31 (0.08, 1.13) 0.0616	
UNINFECTED	207	27 (13.0)	N.A.	205	57 (27.8)	30.16 (14.36, N.A.)	0.44 (0.28, 0.70) 0.0004	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0926
PRESENT	204	19 (9.3)	N.A.	199	62 (31.2)	16.13 (12.91, N.A.)	0.27 (0.16, 0.46) <0.0001	
ABSENT	128	19 (14.8)	N.A.	126	34 (27.0)	N.A. (15.67, N.A.)	0.54 (0.31, 0.95) 0.0302	
BASELINE ALPHA-- FETOPROTEIN								0.0248*
< 400 NG/ML	224	33 (14.7)	N.A.	217	65 (30.0)	N.A. (14.55, N.A.)	0.47 (0.31, 0.71) 0.0003	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	31 (28.7)	30.16 (10.15, N.A.)	0.16 (0.06, 0.41) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Acute Kidney Injury

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	6 (1.8)	N.A.	2.36 (0.89, 6.21) 0.0739	0.7041
AGE								
< 65	162	4 (2.5)	N.A.	143	1 (0.7)	N.A.	3.52 (0.39, 31.62) 0.2302	
>= 65	170	9 (5.3)	N.A.	182	5 (2.7)	N.A.	2.30 (0.77, 6.86) 0.1258	0.9920
SEX								
MALE	269	9 (3.3)	N.A.	269	6 (2.2)	N.A.	1.64 (0.58, 4.63) 0.3422	
FEMALE	63	4 (6.3)	N.A.	56	0	N.E.	N.E. 0.0484	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Acute Kidney Injury

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3597
HBV	98	2 (2.0)	N.A.	95	3 (3.2)	N.A.	0.76 (0.13, 4.53) 0.7583	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	11 (5.3)	N.A.	205	3 (1.5)	N.A.	3.84 (1.07, 13.80) 0.0264	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Acute Kidney Injury

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9873
PRESENT	204	6 (2.9)	N.A.	199	6 (3.0)	N.A.	1.03 (0.33, 3.20) 0.9623	
ABSENT	128	7 (5.5)	N.A.	126	0	N.E.	N.E. 0.0040	
BASELINE ALPHA-- FETOPROTEIN								0.0267*
< 400 NG/ML	224	11 (4.9)	N.A.	217	2 (0.9)	N.A.	6.29 (1.39, 28.39) 0.0061	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	4 (3.7)	N.A.	0.49 (0.09, 2.73) 0.4028	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Proteinuria

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	4 (1.2)	N.A.	325	71 (21.8)	N.A.	0.05 (0.02, 0.14) <0.0001	0.9856
AGE								
< 65	162	0	N.E.	143	34 (23.8)	N.A. (15.67, N.A.)	N.E. <0.0001	
>= 65	170	4 (2.4)	N.A.	182	37 (20.3)	N.A.	0.11 (0.04, 0.32) <0.0001	0.9874
SEX								
MALE	269	4 (1.5)	N.A.	269	61 (22.7)	N.A.	0.06 (0.02, 0.16) <0.0001	
FEMALE	63	0	N.E.	56	10 (17.9)	N.A.	N.E. 0.0007	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Proteinuria

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9997
HBV	98	0	N.E.	95	23 (24.2)	N.A. (16.53, N.A.)	N.E. <0.0001	
HCV	27	0	N.E.	25	8 (32.0)	16.13 (10.15, N.A.)	N.E. 0.0036	
UNINFECTED	207	4 (1.9)	N.A.	205	40 (19.5)	N.A.	0.09 (0.03, 0.25) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Proteinuria

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5942
PRESENT	204	3 (1.5)	N.A.	199	43 (21.6)	N.A. (16.53, N.A.)	0.06 (0.02, 0.19) <0.0001	
ABSENT	128	1 (0.8)	N.A.	126	28 (22.2)	N.A.	0.03 (<0.01, 0.25) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.9077
< 400 NG/ML	224	3 (1.3)	N.A.	217	51 (23.5)	N.A.	0.05 (0.02, 0.16) <0.0001	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	20 (18.5)	N.A.	0.05 (<0.01, 0.38) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	37 (11.1)	N.A. (24.34, N.A.)	325	19 (5.8)	44.81 (N.A., N.A.)	2.37 (1.34, 4.20) 0.0022	0.8375
AGE < 65	162	14 (8.6)	N.A.	143	5 (3.5)	N.A.	2.55 (0.91, 7.09) 0.0640	
>= 65	170	23 (13.5)	24.34 (N.A., N.A.)	182	14 (7.7)	44.81 (N.A., N.A.)	2.51 (1.26, 5.02) 0.0070	
SEX								0.1824
MALE	269	33 (12.3)	N.A.	269	15 (5.6)	44.81 (N.A., N.A.)	2.71 (1.44, 5.07) 0.0012	
FEMALE	63	4 (6.3)	24.34 (N.A., N.A.)	56	4 (7.1)	N.A.	1.18 (0.29, 4.87) 0.8175	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4903
HBV	98	6 (6.1)	N.A.	95	2 (2.1)	N.A.	3.49 (0.70, 17.31) 0.1038	
HCV	27	5 (18.5)	20.70 (19.71, N.A.)	25	1 (4.0)	N.A.	4.61 (0.53, 40.03) 0.1289	
UNINFECTED	207	26 (12.6)	N.A. (24.34, N.A.)	205	16 (7.8)	44.81 (N.A., N.A.)	1.98 (1.05, 3.77) 0.0327	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0196*
PRESENT	204	13 (6.4)	N.A.	199	12 (6.0)	N.A.	1.13 (0.51, 2.49) 0.7669	
ABSENT	128	24 (18.8)	24.34 (24.34, N.A.)	126	7 (5.6)	44.81 (N.A., N.A.)	5.17 (2.09, 12.75) <0.0001	
BASELINE ALPHA-- FETOPROTEIN								0.2010
< 400 NG/ML	224	25 (11.2)	24.34 (24.34, N.A.)	217	16 (7.4)	44.81 (N.A., N.A.)	1.92 (1.00, 3.67) 0.0447	
>= 400 NG/ML	108	12 (11.1)	N.A.	108	3 (2.8)	N.A.	4.84 (1.36, 17.24) 0.0074	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Psychiatric Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	33 (9.9)	N.A.	325	34 (10.5)	N.A.	1.08 (0.67, 1.75) 0.7507	0.8684
AGE < 65	162	16 (9.9)	N.A.	143	15 (10.5)	N.A.	1.04 (0.51, 2.10) 0.9229	
>= 65	170	17 (10.0)	N.A.	182	19 (10.4)	N.A.	1.14 (0.59, 2.20) 0.6866	
SEX								0.2647
MALE	269	25 (9.3)	N.A.	269	30 (11.2)	N.A.	0.95 (0.56, 1.62) 0.8618	
FEMALE	63	8 (12.7)	N.A.	56	4 (7.1)	N.A.	2.00 (0.60, 6.63) 0.2499	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Psychiatric Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8769
HBV	98	7 (7.1)	N.A.	95	6 (6.3)	N.A.	1.35 (0.45, 4.03) 0.5868	
HCV	27	3 (11.1)	N.A. (5.88, N.A.)	25	4 (16.0)	N.A. (13.24, N.A.)	0.89 (0.20, 3.97) 0.8738	
UNINFECTED	207	23 (11.1)	N.A.	205	24 (11.7)	N.A.	1.04 (0.58, 1.84) 0.9056	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Psychiatric Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2307
PRESENT	204	17 (8.3)	N.A.	199	22 (11.1)	N.A.	0.83 (0.44, 1.57) 0.5756	
ABSENT	128	16 (12.5)	N.A.	126	12 (9.5)	N.A.	1.54 (0.73, 3.26) 0.2548	
BASELINE ALPHA-- FETOPROTEIN								0.1070
< 400 NG/ML	224	27 (12.1)	N.A.	217	22 (10.1)	N.A.	1.39 (0.79, 2.43) 0.2544	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	12 (11.1)	N.A.	0.53 (0.20, 1.42) 0.1991	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Psychiatric Disorders. PT: Insomnia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	25 (7.5)	N.A.	325	21 (6.5)	N.A.	1.37 (0.77, 2.46) 0.2809	0.2829
AGE								
< 65	162	11 (6.8)	N.A.	143	11 (7.7)	N.A.	0.97 (0.42, 2.25) 0.9489	
>= 65	170	14 (8.2)	N.A.	182	10 (5.5)	N.A.	1.92 (0.85, 4.32) 0.1101	0.7793
SEX								
MALE	269	20 (7.4)	N.A.	269	18 (6.7)	N.A.	1.32 (0.70, 2.51) 0.3871	
FEMALE	63	5 (7.9)	N.A.	56	3 (5.4)	N.A.	1.70 (0.41, 7.11) 0.4639	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Psychiatric Disorders. PT: Insomnia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8517
HBV	98	5 (5.1)	N.A.	95	3 (3.2)	N.A.	2.03 (0.48, 8.50) 0.3239	
HCV	27	3 (11.1)	N.A. (5.88, N.A.)	25	3 (12.0)	N.A. (13.24, N.A.)	1.27 (0.25, 6.31) 0.7732	
UNINFECTED	207	17 (8.2)	N.A.	205	15 (7.3)	N.A.	1.27 (0.64, 2.55) 0.4944	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Psychiatric Disorders. PT: Insomnia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8081
PRESENT	204	15 (7.4)	N.A.	199	13 (6.5)	N.A.	1.31 (0.62, 2.74) 0.4812	
ABSENT	128	10 (7.8)	N.A.	126	8 (6.3)	N.A.	1.50 (0.59, 3.80) 0.3919	
BASELINE ALPHA-- FETOPROTEIN								0.1655
< 400 NG/ML	224	20 (8.9)	N.A.	217	13 (6.0)	N.A.	1.81 (0.90, 3.64) 0.0920	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	8 (7.4)	N.A.	0.70 (0.23, 2.14) 0.5231	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Eye Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	27 (8.1)	N.A.	325	17 (5.2)	N.A.	1.70 (0.92, 3.13) 0.0868	0.2188
AGE < 65	162	8 (4.9)	N.A.	143	7 (4.9)	N.A.	1.07 (0.38, 2.98) 0.8960	
>= 65	170	19 (11.2)	N.A.	182	10 (5.5)	N.A.	2.37 (1.09, 5.12) 0.0243	
SEX								0.9708
MALE	269	17 (6.3)	N.A.	269	11 (4.1)	N.A.	1.69 (0.79, 3.62) 0.1757	
FEMALE	63	10 (15.9)	N.A.	56	6 (10.7)	N.A. (20.63, N.A.)	1.62 (0.58, 4.49) 0.3506	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Eye Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2374
HBV	98	3 (3.1)	N.A.	95	5 (5.3)	N.A. (22.08, N.A.)	0.59 (0.14, 2.53) 0.4758	
HCV	27	0	N.E.	25	2 (8.0)	N.A.	N.E. 0.2013	
UNINFECTED	207	24 (11.6)	N.A.	205	10 (4.9)	N.A.	2.60 (1.24, 5.47) 0.0088	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Eye Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.7324
PRESENT	204	18 (8.8)	N.A.	199	12 (6.0)	N.A.	1.56 (0.75, 3.26) 0.2350	
ABSENT	128	9 (7.0)	N.A.	126	5 (4.0)	N.A.	2.00 (0.67, 6.02) 0.2057	
BASELINE ALPHA-- FETOPROTEIN								0.5832
< 400 NG/ML	224	21 (9.4)	N.A.	217	12 (5.5)	N.A.	1.87 (0.92, 3.83) 0.0802	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	5 (4.6)	N.A. (20.63, N.A.)	1.24 (0.37, 4.11) 0.7234	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Cardiac Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	21 (6.3)	N.A.	325	29 (8.9)	41.66 (N.A., N.A.)	0.77 (0.44, 1.36) 0.3692	0.2891
AGE < 65	162	9 (5.6)	N.A.	143	14 (9.8)	N.A.	0.61 (0.26, 1.41) 0.2397	
>= 65	170	12 (7.1)	N.A.	182	15 (8.2)	41.66 (N.A., N.A.)	0.97 (0.44, 2.11) 0.9311	
SEX								0.1023
MALE	269	12 (4.5)	N.A.	269	24 (8.9)	41.66 (N.A., N.A.)	0.57 (0.28, 1.15) 0.1096	
FEMALE	63	9 (14.3)	N.A.	56	5 (8.9)	N.A. (22.18, N.A.)	1.56 (0.52, 4.70) 0.4220	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Cardiac Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6875
HBV	98	2 (2.0)	N.A.	95	5 (5.3)	N.A.	0.44 (0.09, 2.28) 0.3160	
HCV	27	2 (7.4)	N.A.	25	2 (8.0)	N.A. (16.36, N.A.)	1.19 (0.17, 8.58) 0.8621	
UNINFECTED	207	17 (8.2)	N.A.	205	22 (10.7)	41.66 (N.A., N.A.)	0.80 (0.42, 1.52) 0.4880	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Cardiac Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1504
PRESENT	204	13 (6.4)	N.A.	199	22 (11.1)	N.A.	0.57 (0.28, 1.14) 0.1084	
ABSENT	128	8 (6.3)	N.A.	126	7 (5.6)	41.66 (N.A., N.A.)	1.50 (0.52, 4.32) 0.4530	
BASELINE ALPHA-- FETOPROTEIN								0.2047
< 400 NG/ML	224	18 (8.0)	N.A.	217	21 (9.7)	41.66 (N.A., N.A.)	0.93 (0.49, 1.77) 0.8344	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	8 (7.4)	N.A.	0.39 (0.10, 1.50) 0.1567	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Ear and Labyrinth Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	N.A.	325	18 (5.5)	N.A.	0.59 (0.27, 1.28) 0.1781	0.7554
AGE < 65	162	4 (2.5)	N.A.	143	7 (4.9)	N.A.	0.54 (0.16, 1.85) 0.3189	
>= 65	170	6 (3.5)	N.A.	182	11 (6.0)	N.A.	0.65 (0.24, 1.78) 0.3993	
SEX								0.5170
MALE	269	9 (3.3)	N.A.	269	15 (5.6)	N.A.	0.69 (0.30, 1.57) 0.3679	
FEMALE	63	1 (1.6)	N.A.	56	3 (5.4)	N.A.	0.23 (0.02, 2.32) 0.1778	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Ear and Labyrinth Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6792
HBV	98	3 (3.1)	N.A.	95	3 (3.2)	N.A.	1.16 (0.23, 5.73) 0.8597	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	7 (3.4)	N.A.	205	15 (7.3)	N.A.	0.47 (0.19, 1.16) 0.0952	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.1
Time to Event Analyses for Any TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Ear and Labyrinth Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2786
PRESENT	204	6 (2.9)	N.A.	199	14 (7.0)	N.A.	0.41 (0.16, 1.09) 0.0657	
ABSENT	128	4 (3.1)	N.A.	126	4 (3.2)	N.A.	1.20 (0.30, 4.81) 0.7931	
BASELINE ALPHA-- FETOPROTEIN								0.4454
< 400 NG/ML	224	8 (3.6)	N.A.	217	12 (5.5)	N.A.	0.72 (0.29, 1.77) 0.4712	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	6 (5.6)	N.A.	0.34 (0.07, 1.69) 0.1660	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	77 (23.2)	N.A. (24.15, N.A.)	325	53 (16.3)	N.A.	1.67 (1.17, 2.37) 0.0041	0.0299*
AGE								
< 65	162	48 (29.6)	N.A. (12.29, N.A.)	143	20 (14.0)	N.A.	2.42 (1.43, 4.08) 0.0006	
>= 65	170	29 (17.1)	24.15 (24.15, N.A.)	182	33 (18.1)	N.A. (18.53, N.A.)	1.14 (0.69, 1.88) 0.6110	0.6046
SEX								
MALE	269	59 (21.9)	24.15 (24.15, N.A.)	269	40 (14.9)	N.A.	1.75 (1.17, 2.61) 0.0061	
FEMALE	63	18 (28.6)	N.A. (6.37, N.A.)	56	13 (23.2)	N.A. (18.37, N.A.)	1.38 (0.67, 2.81) 0.3827	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7603
HBV	98	22 (22.4)	N.A. (12.29, N.A.)	95	13 (13.7)	N.A.	2.03 (1.02, 4.03) 0.0391	
HCV	27	6 (22.2)	N.A. (19.29, N.A.)	25	4 (16.0)	N.A.	1.66 (0.46, 5.97) 0.4393	
UNINFECTED	207	49 (23.7)	N.A. (24.15, N.A.)	205	36 (17.6)	N.A. (18.37, N.A.)	1.53 (0.99, 2.35) 0.0544	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects
SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8795
PRESENT	204	47 (23.0)	N.A.	199	31 (15.6)	N.A.	1.72 (1.09, 2.71) 0.0186	
ABSENT	128	30 (23.4)	24.15 (17.51, N.A.)	126	22 (17.5)	N.A.	1.61 (0.93, 2.80) 0.0888	
BASELINE ALPHA-- FETOPROTEIN								0.9444
< 400 NG/ML	224	52 (23.2)	24.15 (24.15, N.A.)	217	36 (16.6)	N.A.	1.69 (1.10, 2.59) 0.0153	
≥ 400 NG/ML	108	25 (23.1)	N.A.	108	17 (15.7)	N.A. (15.84, N.A.)	1.75 (0.94, 3.25) 0.0736	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	28 (8.4)	N.A.	325	7 (2.2)	N.A.	4.57 (1.99, 10.46) <0.0001	0.5931
AGE								
< 65	162	15 (9.3)	N.A.	143	4 (2.8)	N.A.	3.60 (1.19, 10.86) 0.0150	
≥ 65	170	13 (7.6)	N.A.	182	3 (1.6)	N.A.	5.90 (1.68, 20.71) 0.0017	0.5697
SEX								
MALE	269	22 (8.2)	N.A.	269	5 (1.9)	N.A.	5.29 (2.00, 13.97) 0.0002	
FEMALE	63	6 (9.5)	N.A.	56	2 (3.6)	N.A.	2.88 (0.58, 14.26) 0.1767	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9843
HBV	98	8 (8.2)	N.A.	95	2 (2.1)	N.A.	4.73 (1.00, 22.29) 0.0303	
HCV	27	3 (11.1)	N.A.	25	0	N.E.	N.E. 0.0739	
UNINFECTED	207	17 (8.2)	N.A.	205	5 (2.4)	N.A.	3.90 (1.44, 10.57) 0.0040	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Aspartate Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3282
PRESENT	204	18 (8.8)	N.A.	199	3 (1.5)	N.A.	6.87 (2.02, 23.35) 0.0003	
ABSENT	128	10 (7.8)	N.A.	126	4 (3.2)	N.A.	2.83 (0.89, 9.03) 0.0663	
BASELINE ALPHA-- FETOPROTEIN								0.9864
< 400 NG/ML	224	20 (8.9)	N.A.	217	7 (3.2)	N.A.	3.27 (1.38, 7.74) 0.0043	
≥ 400 NG/ML	108	8 (7.4)	N.A.	108	0	N.E.	N.E. 0.0019	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Lipase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	24 (7.2)	N.A.	325	5 (1.5)	N.A.	5.62 (2.14, 14.73) <0.0001	0.9829
AGE								
< 65	162	16 (9.9)	N.A.	143	3 (2.1)	N.A.	5.35 (1.56, 18.37) 0.0028	
>= 65	170	8 (4.7)	N.A.	182	2 (1.1)	N.A.	5.37 (1.14, 25.30) 0.0172	0.9869
SEX								
MALE	269	17 (6.3)	N.A.	269	5 (1.9)	N.A.	4.00 (1.47, 10.84) 0.0033	
FEMALE	63	7 (11.1)	N.A.	56	0	N.E.	N.E. 0.0063	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Lipase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7636
HBV	98	7 (7.1)	N.A.	95	2 (2.1)	N.A.	4.40 (0.91, 21.17) 0.0434	
HCV	27	0	N.E.	25	1 (4.0)	N.A.	N.E. 0.4292	
UNINFECTED	207	17 (8.2)	N.A.	205	2 (1.0)	N.A.	9.70 (2.24, 42.04) 0.0002	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Lipase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8170
PRESENT	204	16 (7.8)	N.A.	199	3 (1.5)	N.A.	6.26 (1.82, 21.50) 0.0008	
ABSENT	128	8 (6.3)	N.A.	126	2 (1.6)	N.A.	4.70 (1.00, 22.14) 0.0309	
BASELINE ALPHA-- FETOPROTEIN								0.1717
< 400 NG/ML	224	17 (7.6)	N.A.	217	2 (0.9)	N.A.	10.35 (2.39, 44.81) 0.0001	
≥ 400 NG/ML	108	7 (6.5)	N.A.	108	3 (2.8)	N.A.	2.62 (0.67, 10.19) 0.1492	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Alanine Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	23 (6.9)	N.A.	325	6 (1.8)	N.A.	4.39 (1.78, 10.79) 0.0004	0.8810
AGE								
< 65	162	14 (8.6)	N.A.	143	3 (2.1)	N.A.	4.46 (1.28, 15.55) 0.0103	
≥ 65	170	9 (5.3)	N.A.	182	3 (1.6)	N.A.	4.15 (1.12, 15.34) 0.0205	0.7236
SEX								
MALE	269	20 (7.4)	N.A.	269	5 (1.9)	N.A.	4.67 (1.75, 12.48) 0.0007	
FEMALE	63	3 (4.8)	N.A.	56	1 (1.8)	N.A.	3.08 (0.32, 29.63) 0.3047	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Alanine Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9868
HBV	98	7 (7.1)	N.A.	95	2 (2.1)	N.A.	4.21 (0.87, 20.29) 0.0517	
HCV	27	4 (14.8)	N.A. (19.29, N.A.)	25	1 (4.0)	N.A.	3.96 (0.43, 36.28) 0.1903	
UNINFECTED	207	12 (5.8)	N.A.	205	3 (1.5)	N.A.	4.67 (1.32, 16.54) 0.0086	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations. PT: Alanine Aminotransferase Increased

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9855
PRESENT	204	14 (6.9)	N.A.	199	6 (3.0)	N.A.	2.70 (1.04, 7.02) 0.0344	
ABSENT	128	9 (7.0)	N.A.	126	0	N.E.	N.E. 0.0013	
BASELINE ALPHA-- FETOPROTEIN								0.8671
< 400 NG/ML	224	15 (6.7)	N.A.	217	4 (1.8)	N.A.	4.14 (1.37, 12.51) 0.0062	
≥ 400 NG/ML	108	8 (7.4)	N.A.	108	2 (1.9)	N.A.	4.95 (1.05, 23.36) 0.0250	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	54 (16.3)	N.A.	325	45 (13.8)	N.A.	1.33 (0.89, 1.99) 0.1567	0.9509
AGE								
< 65	162	31 (19.1)	N.A.	143	23 (16.1)	N.A.	1.25 (0.72, 2.14) 0.4264	
≥ 65	170	23 (13.5)	N.A.	182	22 (12.1)	N.A.	1.37 (0.76, 2.48) 0.2977	0.6755
SEX								
MALE	269	43 (16.0)	N.A.	269	38 (14.1)	N.A.	1.27 (0.82, 1.98) 0.2863	
FEMALE	63	11 (17.5)	N.A.	56	7 (12.5)	N.A.	1.61 (0.62, 4.14) 0.3231	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1814
HBV	98	20 (20.4)	N.A. (16.56, N.A.)	95	12 (12.6)	N.A.	1.96 (0.96, 4.03) 0.0599	
HCV	27	1 (3.7)	N.A.	25	4 (16.0)	N.A.	0.29 (0.03, 2.63) 0.2430	
UNINFECTED	207	33 (15.9)	N.A.	205	29 (14.1)	N.A.	1.27 (0.77, 2.11) 0.3501	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4781
PRESENT	204	35 (17.2)	N.A.	199	26 (13.1)	N.A. (26.15, N.A.)	1.54 (0.92, 2.58) 0.0971	
ABSENT	128	19 (14.8)	N.A.	126	19 (15.1)	N.A.	1.06 (0.56, 2.01) 0.8501	
BASELINE ALPHA-- FETOPROTEIN								0.5728
< 400 NG/ML	224	36 (16.1)	N.A.	217	27 (12.4)	N.A.	1.40 (0.85, 2.32) 0.1825	
>= 400 NG/ML	108	18 (16.7)	N.A.	108	18 (16.7)	N.A. (26.15, N.A.)	1.20 (0.61, 2.33) 0.5972	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Ascites

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	6 (1.8)	N.A.	2.13 (0.79, 5.75) 0.1286	
AGE								N.M.E.
< 65	162	6 (3.7)	N.M.E.	143	2 (1.4)	N.M.E.	N.M.E.	
≥ 65	170	5 (2.9)	N.M.E.	182	4 (2.2)	N.M.E.	N.M.E.	
SEX								0.4045
MALE	269	9 (3.3)	N.A.	269	4 (1.5)	N.A.	2.67 (0.82, 8.69) 0.0889	
FEMALE	63	2 (3.2)	N.A.	56	2 (3.6)	N.A.	1.01 (0.14, 7.19) 0.9903	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Ascites

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	5 (5.1)	N.M.E.	95	3 (3.2)	N.M.E.	N.M.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	6 (2.9)	N.M.E.	205	3 (1.5)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Ascites

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8689
PRESENT	204	7 (3.4)	N.A.	199	4 (2.0)	N.A.	2.05 (0.60, 7.01) 0.2428	
ABSENT	128	4 (3.1)	N.A.	126	2 (1.6)	N.A.	2.35 (0.43, 12.85) 0.3090	
BASELINE ALPHA-- FETOPROTEIN								0.3709
< 400 NG/ML	224	8 (3.6)	N.A.	217	3 (1.4)	N.A.	3.05 (0.81, 11.52) 0.0828	
≥ 400 NG/ML	108	3 (2.8)	N.A.	108	3 (2.8)	N.A.	1.26 (0.25, 6.27) 0.7745	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	7 (2.1)	N.A.	325	12 (3.7)	N.A.	0.66 (0.26, 1.67) 0.3741	0.3517
AGE								
< 65	162	5 (3.1)	N.A.	143	5 (3.5)	N.A.	0.99 (0.29, 3.43) 0.9903	
>= 65	170	2 (1.2)	N.A.	182	7 (3.8)	N.A.	0.36 (0.07, 1.71) 0.1783	0.3032
SEX								
MALE	269	5 (1.9)	N.A.	269	11 (4.1)	N.A.	0.52 (0.18, 1.50) 0.2188	
FEMALE	63	2 (3.2)	N.A.	56	1 (1.8)	N.A.	2.03 (0.18, 22.44) 0.5539	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9427
HBV	98	2 (2.0)	N.A.	95	2 (2.1)	N.A.	1.24 (0.18, 8.83) 0.8276	
HCV	27	0	N.E.	25	3 (12.0)	N.A.	N.E. 0.1576	
UNINFECTED	207	5 (2.4)	N.A.	205	7 (3.4)	N.A.	0.82 (0.26, 2.59) 0.7387	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders. PT: Diarrhoea

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4733
PRESENT	204	3 (1.5)	N.A.	199	7 (3.5)	N.A.	0.47 (0.12, 1.83) 0.2670	
ABSENT	128	4 (3.1)	N.A.	126	5 (4.0)	N.A.	0.93 (0.25, 3.46) 0.9100	
BASELINE ALPHA-- FETOPROTEIN								0.2288
< 400 NG/ML	224	6 (2.7)	N.A.	217	7 (3.2)	N.A.	0.97 (0.33, 2.88) 0.9538	
≥ 400 NG/ML	108	1 (0.9)	N.A.	108	5 (4.6)	N.A.	0.20 (0.02, 1.75) 0.1076	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	50 (15.1)	N.A.	325	27 (8.3)	N.A. (36.93, N.A.)	2.08 (1.30, 3.35) 0.0020	0.1129
AGE								
< 65	162	20 (12.3)	N.A.	143	14 (9.8)	N.A. (36.93, N.A.)	1.42 (0.71, 2.86) 0.3207	
>= 65	170	30 (17.6)	N.A.	182	13 (7.1)	N.A.	2.87 (1.49, 5.52) 0.0010	0.7920
SEX								
MALE	269	41 (15.2)	N.A.	269	22 (8.2)	N.A. (36.93, N.A.)	2.13 (1.26, 3.62) 0.0040	
FEMALE	63	9 (14.3)	N.A.	56	5 (8.9)	N.A.	1.84 (0.62, 5.49) 0.2672	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8489
HBV	98	10 (10.2)	N.A.	95	5 (5.3)	36.93 (N.A., N.A.)	2.87 (0.90, 9.17) 0.0622	
HCV	27	5 (18.5)	N.A. (16.10, N.A.)	25	2 (8.0)	N.A.	2.47 (0.48, 12.76) 0.2636	
UNINFECTED	207	35 (16.9)	N.A.	205	20 (9.8)	N.A.	1.86 (1.07, 3.23) 0.0261	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.6217
PRESENT	204	32 (15.7)	N.A.	199	15 (7.5)	36.93 (36.93, N.A.)	2.40 (1.28, 4.51) 0.0049	
ABSENT	128	18 (14.1)	N.A.	126	12 (9.5)	N.A.	1.71 (0.82, 3.56) 0.1473	
BASELINE ALPHA-- FETOPROTEIN								0.5935
< 400 NG/ML	224	32 (14.3)	N.A.	217	19 (8.8)	N.A. (36.93, N.A.)	1.92 (1.07, 3.42) 0.0251	
≥ 400 NG/ML	108	18 (16.7)	N.A.	108	8 (7.4)	N.A.	2.49 (1.08, 5.76) 0.0274	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	50 (15.1)	24.51 (N.A., N.A.)	325	76 (23.4)	N.A. (19.15, N.A.)	0.71 (0.49, 1.02) 0.0615	0.9681
AGE								
< 65	162	27 (16.7)	N.A.	143	35 (24.5)	N.A. (17.58, N.A.)	0.71 (0.43, 1.17) 0.1781	
≥ 65	170	23 (13.5)	24.51 (N.A., N.A.)	182	41 (22.5)	N.A. (18.07, N.A.)	0.70 (0.42, 1.18) 0.1774	0.9754
SEX								
MALE	269	43 (16.0)	24.51 (N.A., N.A.)	269	66 (24.5)	26.97 (18.14, N.A.)	0.72 (0.48, 1.06) 0.0906	
FEMALE	63	7 (11.1)	N.A.	56	10 (17.9)	N.A.	0.69 (0.26, 1.83) 0.4536	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0226*
HBV	98	18 (18.4)	N.A. (20.93, N.A.)	95	20 (21.1)	N.A. (18.07, N.A.)	1.01 (0.53, 1.92) 0.9701	
HCV	27	6 (22.2)	N.A. (10.51, N.A.)	25	2 (8.0)	N.A.	3.39 (0.67, 17.04) 0.1162	
UNINFECTED	207	26 (12.6)	24.51 (N.A., N.A.)	205	54 (26.3)	26.97 (15.77, N.A.)	0.50 (0.31, 0.81) 0.0037	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4717
PRESENT	204	32 (15.7)	N.A.	199	52 (26.1)	26.97 (17.58, N.A.)	0.64 (0.41, 1.00) 0.0478	
ABSENT	128	18 (14.1)	24.51 (N.A., N.A.)	126	24 (19.0)	N.A. (20.24, N.A.)	0.87 (0.47, 1.61) 0.6472	
BASELINE ALPHA-- FETOPROTEIN								0.2973
< 400 NG/ML	224	30 (13.4)	24.51 (N.A., N.A.)	217	40 (18.4)	N.A.	0.79 (0.49, 1.27) 0.3320	
≥ 400 NG/ML	108	20 (18.5)	N.A.	108	36 (33.3)	15.24 (9.43, N.A.)	0.63 (0.36, 1.09) 0.0982	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	44 (13.3)	24.51 (N.A., N.A.)	325	68 (20.9)	N.A. (26.97, N.A.)	0.71 (0.48, 1.04) 0.0744	0.6910
AGE < 65	162	24 (14.8)	N.A.	143	29 (20.3)	N.A.	0.76 (0.44, 1.31) 0.3160	
>= 65	170	20 (11.8)	24.51 (N.A., N.A.)	182	39 (21.4)	N.A. (19.15, N.A.)	0.66 (0.38, 1.14) 0.1304	
SEX								0.8664
MALE	269	37 (13.8)	24.51 (N.A., N.A.)	269	59 (21.9)	N.A. (19.15, N.A.)	0.71 (0.47, 1.08) 0.1042	
FEMALE	63	7 (11.1)	N.A. (20.93, N.A.)	56	9 (16.1)	N.A.	0.71 (0.26, 1.93) 0.4967	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0668
HBV	98	15 (15.3)	N.A.	95	18 (18.9)	N.A. (18.07, N.A.)	0.94 (0.47, 1.86) 0.8475	
HCV	27	5 (18.5)	N.A. (10.51, N.A.)	25	2 (8.0)	N.A.	3.14 (0.61, 16.23) 0.1488	
UNINFECTED	207	24 (11.6)	24.51 (N.A., N.A.)	205	48 (23.4)	N.A. (17.58, N.A.)	0.53 (0.32, 0.86) 0.0101	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4087
PRESENT	204	28 (13.7)	N.A.	199	47 (23.6)	N.A. (17.58, N.A.)	0.62 (0.39, 1.00) 0.0499	
ABSENT	128	16 (12.5)	24.51 (N.A., N.A.)	126	21 (16.7)	N.A. (20.24, N.A.)	0.90 (0.46, 1.73) 0.7438	
BASELINE ALPHA-- FETOPROTEIN								0.2695
< 400 NG/ML	224	26 (11.6)	24.51 (N.A., N.A.)	217	34 (15.7)	N.A.	0.82 (0.49, 1.37) 0.4382	
≥ 400 NG/ML	108	18 (16.7)	N.A.	108	34 (31.5)	15.61 (9.43, N.A.)	0.60 (0.33, 1.07) 0.0786	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	46 (13.9)	N.A.	325	33 (10.2)	N.A.	1.55 (0.98, 2.44) 0.0566	0.0693
AGE								
< 65	162	13 (8.0)	N.A.	143	14 (9.8)	N.A.	0.91 (0.42, 1.97) 0.8115	
>= 65	170	33 (19.4)	N.A.	182	19 (10.4)	(30.32, N.A.) N.A.	2.14 (1.21, 3.77) 0.0073	0.7942
SEX								
MALE	269	39 (14.5)	N.A.	269	28 (10.4)	N.A.	1.59 (0.97, 2.60) 0.0629	
FEMALE	63	7 (11.1)	N.A.	56	5 (8.9)	N.A.	1.36 (0.43, 4.28) 0.5990	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5852
HBV	98	9 (9.2)	N.A.	95	6 (6.3)	N.A.	1.64 (0.58, 4.63) 0.3414	
HCV	27	5 (18.5)	N.A. (6.64, N.A.)	25	7 (28.0)	N.A. (6.57, N.A.)	0.81 (0.26, 2.55) 0.7153	
UNINFECTED	207	32 (15.5)	N.A.	205	20 (9.8)	N.A. (30.32, N.A.)	1.74 (0.98, 3.08) 0.0545	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1010
PRESENT	204	26 (12.7)	N.A.	199	24 (12.1)	N.A. (30.32, N.A.)	1.15 (0.65, 2.02) 0.6345	
ABSENT	128	20 (15.6)	N.A.	126	9 (7.1)	N.A.	2.56 (1.17, 5.63) 0.0152	
BASELINE ALPHA-- FETOPROTEIN								0.0182*
< 400 NG/ML	224	33 (14.7)	N.A.	217	15 (6.9)	N.A.	2.33 (1.26, 4.29) 0.0054	
>= 400 NG/ML	108	13 (12.0)	N.A.	108	18 (16.7)	30.32 (30.32, N.A.)	0.85 (0.41, 1.75) 0.6540	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	41 (12.3)	N.A.	325	30 (9.2)	N.A.	1.59 (0.99, 2.57) 0.0538	0.5310
AGE								
< 65	162	18 (11.1)	N.A.	143	9 (6.3)	N.A.	2.23 (0.97, 5.14) 0.0523	
>= 65	170	23 (13.5)	N.A.	182	21 (11.5)	N.A.	1.40 (0.77, 2.53) 0.2693	0.7922
SEX								
MALE	269	33 (12.3)	N.A.	269	24 (8.9)	N.A.	1.59 (0.94, 2.69) 0.0829	
FEMALE	63	8 (12.7)	N.A.	56	6 (10.7)	N.A. (25.00, N.A.)	1.58 (0.52, 4.85) 0.4153	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2234
HBV	98	6 (6.1)	N.A.	95	8 (8.4)	N.A. (25.00, N.A.)	0.94 (0.31, 2.79) 0.9056	
HCV	27	5 (18.5)	N.A. (7.59, N.A.)	25	1 (4.0)	N.A.	5.87 (0.68, 51.04) 0.0701	
UNINFECTED	207	30 (14.5)	N.A.	205	21 (10.2)	N.A.	1.64 (0.94, 2.86) 0.0812	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5768
PRESENT	204	29 (14.2)	N.A.	199	19 (9.5)	N.A.	1.82 (1.01, 3.28) 0.0432	
ABSENT	128	12 (9.4)	N.A.	126	11 (8.7)	N.A.	1.22 (0.54, 2.78) 0.6324	
BASELINE ALPHA-- FETOPROTEIN								0.7195
< 400 NG/ML	224	24 (10.7)	N.A.	217	16 (7.4)	N.A.	1.66 (0.88, 3.13) 0.1144	
>= 400 NG/ML	108	17 (15.7)	N.A.	108	14 (13.0)	N.A. (20.70, N.A.)	1.58 (0.76, 3.26) 0.2131	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyponatraemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	8 (2.5)	N.A.	1.74 (0.71, 4.27) 0.2173	0.6737
AGE								
< 65	162	5 (3.1)	N.A.	143	2 (1.4)	N.A.	2.39 (0.46, 12.33) 0.2831	
≥ 65	170	7 (4.1)	N.A.	182	6 (3.3)	N.A.	1.63 (0.55, 4.84) 0.3769	0.5276
SEX								
MALE	269	10 (3.7)	N.A.	269	6 (2.2)	N.A.	2.00 (0.73, 5.52) 0.1695	
FEMALE	63	2 (3.2)	N.A.	56	2 (3.6)	N.A.	0.95 (0.13, 6.77) 0.9619	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyponatraemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1531
HBV	98	1 (1.0)	N.A.	95	4 (4.2)	N.A.	0.29 (0.03, 2.55) 0.2312	
HCV	27	2 (7.4)	N.A.	25	1 (4.0)	N.A.	2.50 (0.22, 27.72) 0.4411	
UNINFECTED	207	9 (4.3)	N.A.	205	3 (1.5)	N.A.	3.49 (0.94, 12.88) 0.0459	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyponatraemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9574
PRESENT	204	9 (4.4)	N.A.	199	6 (3.0)	N.A.	1.71 (0.61, 4.80) 0.3054	
ABSENT	128	3 (2.3)	N.A.	126	2 (1.6)	N.A.	1.79 (0.30, 10.74) 0.5160	
BASELINE ALPHA-- FETOPROTEIN								0.1568
< 400 NG/ML	224	7 (3.1)	N.A.	217	2 (0.9)	N.A.	4.10 (0.85, 19.76) 0.0560	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	6 (5.6)	N.A.	0.96 (0.29, 3.17) 0.9496	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	1 (0.3)	N.A.	12.89 (1.66, 99.93) 0.0015	
AGE								N.M.E.
< 65	162	5 (3.1)	N.M.E.	143	1 (0.7)	N.M.E.	N.M.E.	
≥ 65	170	6 (3.5)	N.M.E.	182	0	N.E.	N.E.	
SEX								0.9923
MALE	269	9 (3.3)	N.A.	269	1 (0.4)	N.A.	11.07 (1.40, 87.41) 0.0041	
FEMALE	63	2 (3.2)	N.A.	56	0	N.E.	N.E. 0.1604	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	2 (2.0)	N.M.E.	95	1 (1.1)	N.M.E.	N.M.E.	
HCV	27	2 (7.4)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	7 (3.4)	N.M.E.	205	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders. PT: Hyperglycaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	7 (3.4)	N.M.E.	199	1 (0.5)	N.M.E.	N.M.E.	
ABSENT	128	4 (3.1)	N.M.E.	126	0	N.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								N.M.E.
< 400 NG/ML	224	5 (2.2)	N.M.E.	217	1 (0.5)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	6 (5.6)	N.M.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	25 (7.5)	N.A. (24.31, N.A.)	325	21 (6.5)	N.A.	1.43 (0.79, 2.59) 0.2351	0.9188
AGE								
< 65	162	14 (8.6)	N.A.	143	10 (7.0)	N.A.	1.46 (0.63, 3.38) 0.3716	
>= 65	170	11 (6.5)	24.31 (N.A., N.A.)	182	11 (6.0)	N.A.	1.38 (0.59, 3.22) 0.4615	0.3509
SEX								
MALE	269	17 (6.3)	N.A. (24.31, N.A.)	269	17 (6.3)	N.A.	1.15 (0.58, 2.26) 0.6927	
FEMALE	63	8 (12.7)	N.A.	56	4 (7.1)	N.A. (25.03, N.A.)	2.65 (0.70, 9.99) 0.1343	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2807
HBV	98	4 (4.1)	N.A.	95	6 (6.3)	N.A. (25.03, N.A.)	0.83 (0.22, 3.09) 0.7776	
HCV	27	2 (7.4)	N.A. (9.43, N.A.)	25	4 (16.0)	N.A.	0.56 (0.10, 3.09) 0.4956	
UNINFECTED	207	19 (9.2)	N.A. (24.31, N.A.)	205	11 (5.4)	N.A.	2.11 (1.00, 4.46) 0.0453	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9000
PRESENT	204	15 (7.4)	24.31 (24.31, N.A.)	199	12 (6.0)	N.A.	1.57 (0.71, 3.46) 0.2577	
ABSENT	128	10 (7.8)	N.A.	126	9 (7.1)	N.A.	1.25 (0.51, 3.07) 0.6299	
BASELINE ALPHA-- FETOPROTEIN								0.0102*
< 400 NG/ML	224	22 (9.8)	24.31 (24.31, N.A.)	217	11 (5.1)	N.A.	2.40 (1.15, 4.99) 0.0157	
≥ 400 NG/ML	108	3 (2.8)	N.A.	108	10 (9.3)	N.A. (25.03, N.A.)	0.34 (0.09, 1.29) 0.0971	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	11 (3.4)	N.A.	1.34 (0.58, 3.11) 0.4972	0.8593
AGE								
< 65	162	7 (4.3)	N.A.	143	6 (4.2)	N.A.	1.34 (0.43, 4.24) 0.6131	
>= 65	170	5 (2.9)	N.A.	182	5 (2.7)	N.A.	1.24 (0.36, 4.33) 0.7356	0.5160
SEX								
MALE	269	7 (2.6)	N.A.	269	8 (3.0)	N.A.	0.99 (0.36, 2.75) 0.9872	
FEMALE	63	5 (7.9)	N.A.	56	3 (5.4)	N.A. (25.03, N.A.)	2.50 (0.49, 12.91) 0.2559	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9493
HBV	98	3 (3.1)	N.A.	95	3 (3.2)	N.A. (25.03, N.A.)	1.61 (0.27, 9.65) 0.6010	
HCV	27	0	N.E.	25	2 (8.0)	N.A. (16.36, N.A.)	N.E. 0.1591	
UNINFECTED	207	9 (4.3)	N.A.	205	6 (2.9)	N.A.	1.74 (0.62, 4.88) 0.2890	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Blood and Lymphatic System Disorders. PT: Anaemia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9198
PRESENT	204	7 (3.4)	N.A.	199	6 (3.0)	N.A.	1.51 (0.48, 4.80) 0.4789	
ABSENT	128	5 (3.9)	N.A.	126	5 (4.0)	N.A.	1.19 (0.34, 4.12) 0.7809	
BASELINE ALPHA-- FETOPROTEIN								0.0658
< 400 NG/ML	224	10 (4.5)	N.A.	217	5 (2.3)	N.A.	2.32 (0.79, 6.80) 0.1130	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	6 (5.6)	N.A. (25.03, N.A.)	0.35 (0.07, 1.88) 0.2049	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	25 (7.5)	N.A.	325	31 (9.5)	N.A.	0.88 (0.52, 1.49) 0.6258	0.1218
AGE								
< 65	162	10 (6.2)	N.A.	143	5 (3.5)	N.A.	1.93 (0.66, 5.66) 0.2211	
≥ 65	170	15 (8.8)	N.A.	182	26 (14.3)	N.A.	0.71 (0.37, 1.33) 0.2803	0.3504
SEX								
MALE	269	22 (8.2)	N.A.	269	25 (9.3)	N.A.	0.99 (0.56, 1.75) 0.9669	
FEMALE	63	3 (4.8)	N.A.	56	6 (10.7)	N.A.	0.47 (0.12, 1.87) 0.2713	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1624
HBV	98	9 (9.2)	N.A.	95	6 (6.3)	N.A.	1.72 (0.61, 4.85) 0.2962	
HCV	27	3 (11.1)	N.A. (9.23, N.A.)	25	2 (8.0)	N.A. (16.16, N.A.)	1.87 (0.31, 11.36) 0.4905	
UNINFECTED	207	13 (6.3)	N.A.	205	23 (11.2)	N.A.	0.60 (0.31, 1.19) 0.1426	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2499
PRESENT	204	17 (8.3)	N.A.	199	16 (8.0)	N.A.	1.14 (0.58, 2.26) 0.7067	
ABSENT	128	8 (6.3)	N.A.	126	15 (11.9)	N.A.	0.59 (0.25, 1.40) 0.2274	
BASELINE ALPHA-- FETOPROTEIN								0.0523
< 400 NG/ML	224	13 (5.8)	N.A.	217	24 (11.1)	N.A.	0.59 (0.30, 1.16) 0.1193	
≥ 400 NG/ML	108	12 (11.1)	N.A.	108	7 (6.5)	N.A.	1.89 (0.74, 4.81) 0.1775	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	22 (6.6)	N.A.	325	23 (7.1)	N.A.	1.11 (0.62, 2.01) 0.7224	0.1087
AGE								
< 65	162	10 (6.2)	N.A.	143	14 (9.8)	N.A.	0.72 (0.32, 1.64) 0.4335	
>= 65	170	12 (7.1)	N.A.	182	9 (4.9)	N.A.	1.75 (0.74, 4.17) 0.1984	0.0754
SEX								
MALE	269	19 (7.1)	N.A.	269	15 (5.6)	N.A.	1.46 (0.74, 2.87) 0.2727	
FEMALE	63	3 (4.8)	N.A.	56	8 (14.3)	N.A. (24.80, N.A.)	0.43 (0.11, 1.65) 0.2019	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5325
HBV	98	7 (7.1)	N.A.	95	5 (5.3)	N.A. (24.80, N.A.)	1.98 (0.58, 6.77) 0.2686	
HCV	27	3 (11.1)	N.A.	25	0	N.E.	N.E. 0.0566	
UNINFECTED	207	12 (5.8)	N.A.	205	18 (8.8)	N.A.	0.71 (0.34, 1.48) 0.3549	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0798
PRESENT	204	11 (5.4)	N.A.	199	17 (8.5)	N.A.	0.74 (0.34, 1.59) 0.4326	
ABSENT	128	11 (8.6)	N.A.	126	6 (4.8)	N.A.	2.14 (0.79, 5.78) 0.1261	
BASELINE ALPHA-- FETOPROTEIN								0.8937
< 400 NG/ML	224	16 (7.1)	N.A.	217	17 (7.8)	N.A.	1.04 (0.53, 2.06) 0.9048	
≥ 400 NG/ML	108	6 (5.6)	N.A.	108	6 (5.6)	N.A. (24.80, N.A.)	1.27 (0.38, 4.21) 0.7002	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Palmar-Plantar Erythrodysesthesia Syndrome

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	0	N.E.	325	13 (4.0)	N.A.	N.E. 0.0007	N.M.E.
AGE								
< 65	162	0	N.E.	143	6 (4.2)	N.M.E.	N.E.	
≥ 65	170	0	N.E.	182	7 (3.8)	N.M.E.	N.E.	
SEX								
MALE	269	0	N.E.	269	9 (3.3)	N.M.E.	N.E.	N.M.E.
FEMALE	63	0	N.E.	56	4 (7.1)	N.M.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Palmar-Plantar Erythrodysaesthesia Syndrome

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	0	N.E.	95	2 (2.1)	N.A.	N.E. 0.1835	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	0	N.E.	205	11 (5.4)	N.A.	N.E. 0.0015	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

- (1) KME of median time to first AE.
- (2) Hazard ratio from unstratified Cox proportional hazard model.
- (3) p-value from unstratified log-rank test.
- (4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0
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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders. PT: Palmar-Plantar Erythrodysesthesia Syndrome

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	9 (4.5)	N.M.E.	N.E.	
ABSENT	128	0	N.E.	126	4 (3.2)	N.M.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								>0.9999
< 400 NG/ML	224	0	N.E.	217	10 (4.6)	N.A.	N.E. 0.0028	
$\geq$ 400 NG/ML	108	0	N.E.	108	3 (2.8)	N.A.	N.E. 0.1233	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	19 (5.7)	N.A.	325	17 (5.2)	N.A.	1.23 (0.64, 2.36) 0.5435	0.0458*
AGE								
< 65	162	2 (1.2)	N.A.	143	6 (4.2)	N.A.	0.27 (0.05, 1.36) 0.0911	
>= 65	170	17 (10.0)	N.A.	182	11 (6.0)	N.A.	2.03 (0.95, 4.34) 0.0620	0.2392
SEX								
MALE	269	15 (5.6)	N.A.	269	11 (4.1)	N.A.	1.60 (0.74, 3.49) 0.2314	
FEMALE	63	4 (6.3)	N.A.	56	6 (10.7)	N.A. (18.86, N.A.)	0.59 (0.16, 2.10) 0.4084	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3101
HBV	98	2 (2.0)	N.A.	95	5 (5.3)	N.A.	0.41 (0.08, 2.10) 0.2655	
HCV	27	2 (7.4)	N.A.	25	3 (12.0)	N.A. (11.83, N.A.)	0.88 (0.15, 5.29) 0.8862	
UNINFECTED	207	15 (7.2)	N.A.	205	9 (4.4)	N.A.	1.86 (0.81, 4.26) 0.1358	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8898
PRESENT	204	14 (6.9)	N.A.	199	12 (6.0)	N.A.	1.28 (0.59, 2.77) 0.5354	
ABSENT	128	5 (3.9)	N.A.	126	5 (4.0)	N.A.	1.08 (0.31, 3.74) 0.9027	
BASELINE ALPHA-- FETOPROTEIN								0.3205
< 400 NG/ML	224	13 (5.8)	N.A.	217	14 (6.5)	N.A.	1.01 (0.47, 2.15) 0.9845	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	3 (2.8)	N.A.	2.07 (0.51, 8.47) 0.3012	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	18 (5.4)	N.A.	325	52 (16.0)	N.A.	0.34 (0.20, 0.58) <0.0001	0.1979
AGE								
< 65	162	6 (3.7)	N.A.	143	23 (16.1)	N.A.	0.21 (0.09, 0.53) 0.0002	
≥ 65	170	12 (7.1)	N.A.	182	29 (15.9)	N.A.	0.47 (0.24, 0.93) 0.0254	0.3667
SEX								
MALE	269	13 (4.8)	N.A.	269	35 (13.0)	N.A.	0.37 (0.19, 0.70) 0.0015	0.63
FEMALE	63	5 (7.9)	N.A.	56	17 (30.4)	N.A. (6.51, N.A.)	0.23 (0.09, 0.63) 0.0018	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0530
HBV	98	1 (1.0)	N.A.	95	18 (18.9)	N.A.	0.05 (<0.01, <0.0001	0.40)
HCV	27	4 (14.8)	N.A. (19.71, N.A.)	25	4 (16.0)	N.A. (14.82, N.A.)	1.03 (0.25, 0.9695	4.16)
UNINFECTED	207	13 (6.3)	N.A.	205	30 (14.6)	N.A.	0.42 (0.22, 0.0077	0.81)

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3497
PRESENT	204	8 (3.9)	N.A.	199	29 (14.6)	N.A.	0.26 (0.12, 0.58) 0.0004	
ABSENT	128	10 (7.8)	N.A.	126	23 (18.3)	N.A.	0.44 (0.21, 0.93) 0.0278	
BASELINE ALPHA-- FETOPROTEIN								0.5203
< 400 NG/ML	224	15 (6.7)	N.A.	217	39 (18.0)	N.A.	0.36 (0.20, 0.66) 0.0005	
≥ 400 NG/ML	108	3 (2.8)	N.A.	108	13 (12.0)	N.A.	0.26 (0.08, 0.93) 0.0259	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypertension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	43 (13.2)	N.A.	0.28 (0.15, 0.53) <0.0001	0.1585
AGE								
< 65	162	3 (1.9)	N.A.	143	18 (12.6)	N.A.	0.14 (0.04, 0.48) 0.0003	
>= 65	170	9 (5.3)	N.A.	182	25 (13.7)	N.A.	0.42 (0.20, 0.91) 0.0233	0.3922
SEX								
MALE	269	9 (3.3)	N.A.	269	29 (10.8)	N.A.	0.32 (0.15, 0.67) 0.0016	
FEMALE	63	3 (4.8)	N.A.	56	14 (25.0)	N.A.	0.18 (0.05, 0.63) 0.0024	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypertension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.1252
HBV	98	1 (1.0)	N.A.	95	16 (16.8)	N.A.	0.06 (<0.01, 0.0002 0.46)	
HCV	27	2 (7.4)	N.A.	25	2 (8.0)	N.A.	1.16 (0.16, 0.8809 8.27)	
UNINFECTED	207	9 (4.3)	N.A.	205	25 (12.2)	N.A.	0.36 (0.17, 0.0065 0.78)	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders. PT: Hypertension

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3666
PRESENT	204	5 (2.5)	N.A.	199	24 (12.1)	N.A.	0.20 (0.08, 0.54) 0.0004	
ABSENT	128	7 (5.5)	N.A.	126	19 (15.1)	N.A.	0.39 (0.16, 0.92) 0.0256	
BASELINE ALPHA-- FETOPROTEIN								0.4923
< 400 NG/ML	224	10 (4.5)	N.A.	217	31 (14.3)	N.A.	0.31 (0.15, 0.64) 0.0008	
≥ 400 NG/ML	108	2 (1.9)	N.A.	108	12 (11.1)	N.A.	0.20 (0.04, 0.89) 0.0191	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	15 (4.5)	N.A.	325	8 (2.5)	N.A.	2.12 (0.90, 5.00) 0.0803	0.5986
AGE								
< 65	162	5 (3.1)	N.A.	143	3 (2.1)	N.A.	1.72 (0.41, 7.18) 0.4543	
>= 65	170	10 (5.9)	N.A.	182	5 (2.7)	N.A.	2.52 (0.86, 7.38) 0.0822	0.9332
SEX								
MALE	269	11 (4.1)	N.A.	269	6 (2.2)	N.A.	2.13 (0.79, 5.78) 0.1276	
FEMALE	63	4 (6.3)	N.A.	56	2 (3.6)	N.A.	1.96 (0.36, 10.70) 0.4291	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7945
HBV	98	4 (4.1)	N.A.	95	3 (3.2)	N.A.	1.66 (0.37, 7.44) 0.5007	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A. (14.42, N.A.)	1.29 (0.08, 20.56) 0.8586	
UNINFECTED	207	10 (4.8)	N.A.	205	4 (2.0)	N.A.	2.77 (0.87, 8.86) 0.0729	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4171
PRESENT	204	9 (4.4)	N.A.	199	6 (3.0)	N.A.	1.59 (0.56, 4.48) 0.3769	
ABSENT	128	6 (4.7)	N.A.	126	2 (1.6)	N.A.	3.68 (0.74, 18.22) 0.0875	
BASELINE ALPHA-- FETOPROTEIN								0.4403
< 400 NG/ML	224	8 (3.6)	N.A.	217	3 (1.4)	N.A.	3.10 (0.82, 11.68) 0.0784	
≥ 400 NG/ML	108	7 (6.5)	N.A.	108	5 (4.6)	N.A.	1.42 (0.44, 4.54) 0.5555	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	0	N.E.	N.E. <0.0001	
AGE								N.M.E.
< 65	162	7 (4.3)	N.M.E.	143	0	N.E.	N.E.	
≥ 65	170	6 (3.5)	N.M.E.	182	0	N.E.	N.E.	
SEX								>0.9999
MALE	269	11 (4.1)	N.A.	269	0	N.E.	N.E. 0.0002	
FEMALE	63	2 (3.2)	N.A.	56	0	N.E.	N.E. 0.1432	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	3 (3.1)	N.A.	95	0	N.E.	N.E. 0.0477	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	10 (4.8)	N.A.	205	0	N.E.	N.E. 0.0005	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9994
PRESENT	204	12 (5.9)	N.A.	199	0	N.E.	N.E. 0.0001	
ABSENT	128	1 (0.8)	N.A.	126	0	N.E.	N.E. 0.2822	
BASELINE ALPHA-- FETOPROTEIN								>0.9999
< 400 NG/ML	224	10 (4.5)	N.A.	217	0	N.E.	N.E. 0.0006	
≥ 400 NG/ML	108	3 (2.8)	N.A.	108	0	N.E.	N.E. 0.0430	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	6 (1.8)	N.A.	2.03 (0.76, 5.43) 0.1504	0.9779
AGE								
< 65	162	7 (4.3)	N.A.	143	3 (2.1)	N.A.	2.01 (0.52, 7.81) 0.3045	
>= 65	170	5 (2.9)	N.A.	182	3 (1.6)	N.A.	2.00 (0.48, 8.41) 0.3332	0.6269
SEX								
MALE	269	9 (3.3)	N.A.	269	4 (1.5)	N.A.	2.43 (0.75, 7.92) 0.1277	
FEMALE	63	3 (4.8)	N.A.	56	2 (3.6)	N.A. (20.53, N.A.)	1.19 (0.19, 7.31) 0.8506	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5998
HBV	98	4 (4.1)	N.A.	95	1 (1.1)	N.A.	4.52 (0.50, 40.49) 0.1395	
HCV	27	2 (7.4)	N.A.	25	0	N.E.	N.E. 0.1003	
UNINFECTED	207	6 (2.9)	N.A.	205	5 (2.4)	N.A.	1.12 (0.34, 3.70) 0.8582	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects
SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	7 (3.4)	N.M.E.	199	2 (1.0)	N.M.E.	N.M.E.	
ABSENT	128	5 (3.9)	N.M.E.	126	4 (3.2)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								0.2831
< 400 NG/ML	224	9 (4.0)	N.A.	217	3 (1.4)	N.A.	3.22 (0.87, 11.90) 0.0637	
≥ 400 NG/ML	108	3 (2.8)	N.A.	108	3 (2.8)	N.A. (20.53, N.A.)	0.83 (0.16, 4.31) 0.8286	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	28 (8.6)	N.A.	0.44 (0.22, 0.88) 0.0173	0.3819
AGE								
< 65	162	4 (2.5)	N.A.	143	5 (3.5)	N.A.	0.91 (0.23, 3.64) 0.8918	
>= 65	170	7 (4.1)	N.A.	182	23 (12.6)	(30.16, N.A.) N.A.	0.38 (0.16, 0.88) 0.0189	0.0989
SEX								
MALE	269	7 (2.6)	N.A.	269	25 (9.3)	N.A.	0.32 (0.14, 0.74) 0.0048	0.0989
FEMALE	63	4 (6.3)	N.A.	56	3 (5.4)	N.A.	1.28 (0.29, 5.73) 0.7438	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8101
HBV	98	2 (2.0)	N.A.	95	8 (8.4)	N.A.	0.27 (0.06, 1.27) 0.0756	
HCV	27	1 (3.7)	N.A.	25	3 (12.0)	N.A. (16.13, N.A.)	0.38 (0.04, 3.62) 0.3788	
UNINFECTED	207	8 (3.9)	N.A.	205	17 (8.3)	N.A.	0.53 (0.22, 1.23) 0.1325	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.0240*
PRESENT	204	3 (1.5)	N.A.	199	19 (9.5)	N.A.	0.16 (0.05, 0.55) 0.0008	
ABSENT	128	8 (6.3)	N.A.	126	9 (7.1)	N.A. (30.16, N.A.)	1.12 (0.42, 2.99) 0.8185	
BASELINE ALPHA-- FETOPROTEIN								0.3711
< 400 NG/ML	224	9 (4.0)	N.A.	217	19 (8.8)	N.A.	0.54 (0.24, 1.20) 0.1253	
$\geq$ 400 NG/ML	108	2 (1.9)	N.A.	108	9 (8.3)	N.A.	0.22 (0.05, 1.05) 0.0379	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Proteinuria

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	0	N.E.	325	17 (5.2)	N.A.	N.E. 0.0001	0.9997
AGE								
< 65	162	0	N.E.	143	4 (2.8)	N.A. (30.16, N.A.)	N.E. 0.0773	
>= 65	170	0	N.E.	182	13 (7.1)	N.A.	N.E. 0.0012	0.9999
SEX								
MALE	269	0	N.E.	269	15 (5.6)	N.A.	N.E. 0.0004	
FEMALE	63	0	N.E.	56	2 (3.6)	N.A.	N.E. 0.1558	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.2
Time to Event Analyses for Severe TEAE (Grade >=3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Proteinuria

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	0	N.E.	95	3 (3.2)	N.A.	N.E. 0.0895	
HCV	27	0	N.E.	25	2 (8.0)	N.A. (16.13, N.A.)	N.E. 0.1617	
UNINFECTED	207	0	N.E.	205	12 (5.9)	N.A.	N.E. 0.0017	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
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Table 12.2
Time to Event Analyses for Severe TEAE (Grade ≥ 3)
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders. PT: Proteinuria

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	9 (4.5)	N.M.E.	N.E.	
ABSENT	128	0	N.E.	126	8 (6.3)	N.M.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								0.9998
< 400 NG/ML	224	0	N.E.	217	14 (6.5)	N.A.	N.E. 0.0005	
$\geq$ 400 NG/ML	108	0	N.E.	108	3 (2.8)	N.A.	N.E. 0.0941	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	51 (15.4)	24.51 (N.A., N.A.)	325	75 (23.1)	N.A. (18.23, N.A.)	0.74 (0.51, 1.06) 0.0959	0.7797
AGE < 65	162	29 (17.9)	N.A.	143	35 (24.5)	N.A. (17.58, N.A.)	0.76 (0.46, 1.24) 0.2651	
>= 65	170	22 (12.9)	24.51 (N.A., N.A.)	182	40 (22.0)	N.A. (18.07, N.A.)	0.70 (0.41, 1.19) 0.1817	
SEX								0.6834
MALE	269	45 (16.7)	24.51 (N.A., N.A.)	269	65 (24.2)	26.97 (18.07, N.A.)	0.76 (0.52, 1.12) 0.1705	
FEMALE	63	6 (9.5)	N.A.	56	10 (17.9)	N.A.	0.60 (0.21, 1.66) 0.3174	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0179*
HBV	98	20 (20.4)	N.A. (20.93, N.A.)	95	21 (22.1)	N.A. (16.39, N.A.)	1.07 (0.58, 1.97) 0.8345	
HCV	27	6 (22.2)	N.A. (10.51, N.A.)	25	2 (8.0)	N.A.	3.39 (0.67, 17.04) 0.1162	
UNINFECTED	207	25 (12.1)	24.51 (N.A., N.A.)	205	52 (25.4)	26.97 (15.77, N.A.)	0.51 (0.31, 0.82) 0.0052	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2894
PRESENT	204	33 (16.2)	N.A.	199	54 (27.1)	18.23 (15.61, N.A.)	0.64 (0.41, 0.99) 0.0443	
ABSENT	128	18 (14.1)	24.51 (N.A., N.A.)	126	21 (16.7)	N.A. (20.24, N.A.)	0.99 (0.52, 1.87) 0.9759	
BASELINE ALPHA-- FETOPROTEIN								0.1209
< 400 NG/ML	224	32 (14.3)	24.51 (N.A., N.A.)	217	38 (17.5)	N.A.	0.90 (0.56, 1.44) 0.6542	
>= 400 NG/ML	108	19 (17.6)	N.A.	108	37 (34.3)	15.24 (9.43, 26.97)	0.57 (0.33, 1.00) 0.0492	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	44 (13.3)	24.51 (N.A., N.A.)	325	67 (20.6)	N.A. (26.97, N.A.)	0.72 (0.49, 1.06) 0.0969	0.5783
AGE < 65	162	25 (15.4)	N.A.	143	29 (20.3)	N.A.	0.79 (0.46, 1.35) 0.3822	
>= 65	170	19 (11.2)	24.51 (N.A., N.A.)	182	38 (20.9)	N.A. (19.15, N.A.)	0.66 (0.38, 1.15) 0.1362	
SEX								0.8537
MALE	269	38 (14.1)	24.51 (N.A., N.A.)	269	58 (21.6)	N.A. (19.15, N.A.)	0.75 (0.49, 1.13) 0.1681	
FEMALE	63	6 (9.5)	N.A. (20.93, N.A.)	56	9 (16.1)	N.A.	0.61 (0.21, 1.74) 0.3490	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0526
HBV	98	16 (16.3)	N.A.	95	18 (18.9)	N.A. (18.07, N.A.)	0.99 (0.51, 1.95) 0.9837	
HCV	27	5 (18.5)	N.A. (10.51, N.A.)	25	2 (8.0)	N.A.	3.14 (0.61, 16.23) 0.1488	
UNINFECTED	207	23 (11.1)	24.51 (N.A., N.A.)	205	47 (22.9)	N.A. (17.58, N.A.)	0.52 (0.32, 0.87) 0.0108	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3925
PRESENT	204	29 (14.2)	N.A.	199	48 (24.1)	N.A. (16.39, N.A.)	0.64 (0.40, 1.02) 0.0610	
ABSENT	128	15 (11.7)	24.51 (N.A., N.A.)	126	19 (15.1)	N.A.	0.93 (0.47, 1.85) 0.8395	
BASELINE ALPHA-- FETOPROTEIN								0.1845
< 400 NG/ML	224	26 (11.6)	24.51 (N.A., N.A.)	217	32 (14.7)	N.A.	0.88 (0.52, 1.49) 0.6318	
>= 400 NG/ML	108	18 (16.7)	N.A.	108	35 (32.4)	15.61 (9.43, N.A.)	0.57 (0.32, 1.02) 0.0558	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	50 (15.1)	N.A.	325	40 (12.3)	N.A.	1.36 (0.89, 2.08) 0.1471	0.9954
AGE								
< 65	162	27 (16.7)	N.A.	143	19 (13.3)	N.A.	1.30 (0.72, 2.34) 0.3850	
>= 65	170	23 (13.5)	N.A.	182	21 (11.5)	N.A.	1.39 (0.76, 2.55) 0.2761	0.7193
SEX								
MALE	269	37 (13.8)	N.A.	269	32 (11.9)	N.A.	1.29 (0.79, 2.08) 0.3045	
FEMALE	63	13 (20.6)	N.A. (10.48, N.A.)	56	8 (14.3)	N.A.	1.54 (0.64, 3.73) 0.3304	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4086
HBV	98	16 (16.3)	N.A. (19.19, N.A.)	95	11 (11.6)	N.A. (19.42, N.A.)	1.67 (0.77, 3.61) 0.1870	
HCV	27	1 (3.7)	N.A.	25	3 (12.0)	N.A.	0.34 (0.04, 3.24) 0.3250	
UNINFECTED	207	33 (15.9)	N.A.	205	26 (12.7)	N.A.	1.41 (0.84, 2.38) 0.1927	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4120
PRESENT	204	33 (16.2)	N.A.	199	23 (11.6)	N.A. (26.15, N.A.)	1.61 (0.94, 2.77) 0.0810	
ABSENT	128	17 (13.3)	N.A.	126	17 (13.5)	N.A.	1.05 (0.53, 2.06) 0.8908	
BASELINE ALPHA-- FETOPROTEIN								0.4288
< 400 NG/ML	224	33 (14.7)	N.A.	217	23 (10.6)	N.A.	1.48 (0.87, 2.53) 0.1452	
>= 400 NG/ML	108	17 (15.7)	N.A.	108	17 (15.7)	N.A. (15.21, N.A.)	1.15 (0.58, 2.30) 0.6819	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva		Test for Interaction P-value (4)(5)
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)		
OVERALL	332	48 (14.5)	N.A.	325	33 (10.2)	N.A.	1.58 (1.01, 2.48) 0.0436		
AGE									0.0896
< 65	162	14 (8.6)	N.A.	143	14 (9.8)	N.A.	0.96 (0.45, 2.05) 0.9108		
>= 65	170	34 (20.0)	N.A.	182	19 (10.4)	(30.32, N.A.) N.A.	2.15 (1.23, 3.78) 0.0063		
SEX									0.6396
MALE	269	40 (14.9)	N.A.	269	27 (10.0)	N.A.	1.69 (1.03, 2.78) 0.0353		
FEMALE	63	8 (12.7)	N.A. (20.50, N.A.)	56	6 (10.7)	N.A. (18.73, N.A.)	1.15 (0.39, 3.34) 0.8018		

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4964
HBV	98	9 (9.2)	N.A.	95	7 (7.4)	N.A.	1.43 (0.53, 3.85) 0.4725	
HCV	27	5 (18.5)	N.A. (6.64, N.A.)	25	7 (28.0)	N.A. (6.57, N.A.)	0.81 (0.26, 2.56) 0.7223	
UNINFECTED	207	34 (16.4)	N.A.	205	19 (9.3)	N.A. (30.32, N.A.)	1.89 (1.06, 3.36) 0.0277	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3196
PRESENT	204	29 (14.2)	N.A.	199	23 (11.6)	N.A. (30.32, N.A.)	1.32 (0.75, 2.30) 0.3349	
ABSENT	128	19 (14.8)	N.A.	126	10 (7.9)	N.A.	2.14 (0.99, 4.61) 0.0461	
BASELINE ALPHA-- FETOPROTEIN								0.0288*
< 400 NG/ML	224	32 (14.3)	N.A.	217	14 (6.5)	N.A.	2.41 (1.29, 4.53) 0.0046	
>= 400 NG/ML	108	16 (14.8)	N.A.	108	19 (17.6)	30.32 (14.42, N.A.)	0.88 (0.45, 1.75) 0.7240	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	41 (12.3)	N.A.	325	21 (6.5)	N.A. (36.93, N.A.)	2.27 (1.33, 3.88) 0.0020	0.3402
AGE < 65	162	19 (11.7)	N.A.	143	11 (7.7)	N.A. (36.93, N.A.)	1.77 (0.82, 3.81) 0.1401	
>= 65	170	22 (12.9)	N.A.	182	10 (5.5)	N.A.	2.81 (1.33, 5.93) 0.0049	
SEX								0.5153
MALE	269	33 (12.3)	N.A.	269	16 (5.9)	N.A. (36.93, N.A.)	2.48 (1.34, 4.57) 0.0026	
FEMALE	63	8 (12.7)	N.A.	56	5 (8.9)	N.A.	1.60 (0.52, 4.88) 0.4097	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9920
HBV	98	9 (9.2)	N.A.	95	5 (5.3)	36.93 (N.A., N.A.)	2.60 (0.80, 8.44) 0.0997	
HCV	27	4 (14.8)	N.A. (16.10, N.A.)	25	0	N.E.	N.E. 0.0446	
UNINFECTED	207	28 (13.5)	N.A.	205	16 (7.8)	N.A.	1.89 (1.02, 3.51) 0.0394	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9186
PRESENT	204	26 (12.7)	N.A.	199	13 (6.5)	36.93 (36.93, N.A.)	2.28 (1.15, 4.54) 0.0152	
ABSENT	128	15 (11.7)	N.A.	126	8 (6.3)	N.A.	2.23 (0.95, 5.27) 0.0602	
BASELINE ALPHA-- FETOPROTEIN								0.4532
< 400 NG/ML	224	23 (10.3)	N.A.	217	14 (6.5)	N.A. (36.93, N.A.)	1.96 (0.99, 3.87) 0.0486	
>= 400 NG/ML	108	18 (16.7)	N.A.	108	7 (6.5)	N.A.	2.90 (1.21, 6.99) 0.0129	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	18 (5.4)	25.26 (N.A., N.A.)	325	20 (6.2)	N.A.	1.09 (0.57, 2.10) 0.7871	0.0914
AGE < 65	162	2 (1.2)	N.A.	143	6 (4.2)	N.A.	0.27 (0.05, 1.36) 0.0890	
>= 65	170	16 (9.4)	25.26 (N.A., N.A.)	182	14 (7.7)	N.A. (30.23, N.A.)	1.74 (0.83, 3.66) 0.1386	
SEX								0.7125
MALE	269	13 (4.8)	25.26 (N.A., N.A.)	269	14 (5.2)	N.A.	1.26 (0.58, 2.75) 0.5661	
FEMALE	63	5 (7.9)	N.A.	56	6 (10.7)	N.A. (18.86, N.A.)	0.76 (0.23, 2.50) 0.6533	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5197
HBV	98	2 (2.0)	N.A.	95	4 (4.2)	N.A.	0.51 (0.09, 2.79) 0.4275	
HCV	27	1 (3.7)	N.A.	25	3 (12.0)	N.A. (11.83, N.A.)	0.45 (0.05, 4.33) 0.4750	
UNINFECTED	207	15 (7.2)	25.26 (N.A., N.A.)	205	13 (6.3)	N.A. (30.23, N.A.)	1.50 (0.69, 3.25) 0.3019	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9937
PRESENT	204	12 (5.9)	25.26 (N.A., N.A.)	199	13 (6.5)	N.A.	1.07 (0.48, 2.38) 0.8655	
ABSENT	128	6 (4.7)	N.A.	126	7 (5.6)	N.A. (30.23, N.A.)	1.11 (0.36, 3.45) 0.8561	
BASELINE ALPHA-- FETOPROTEIN								0.8370
< 400 NG/ML	224	13 (5.8)	25.26 (N.A., N.A.)	217	15 (6.9)	N.A.	1.08 (0.50, 2.33) 0.8447	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	5 (4.6)	N.A.	1.04 (0.29, 3.67) 0.9531	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	17 (5.1)	N.A.	325	25 (7.7)	N.A.	0.76 (0.41, 1.41) 0.3814	0.4743
AGE < 65	162	7 (4.3)	N.A.	143	6 (4.2)	N.A.	1.16 (0.39, 3.45) 0.7901	
>= 65	170	10 (5.9)	N.A.	182	19 (10.4)	N.A.	0.67 (0.31, 1.44) 0.2994	
SEX								0.1164
MALE	269	16 (5.9)	N.A.	269	19 (7.1)	N.A.	0.98 (0.50, 1.90) 0.9430	
FEMALE	63	1 (1.6)	N.A.	56	6 (10.7)	N.A.	0.16 (0.02, 1.36) 0.0562	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6179
HBV	98	6 (6.1)	N.A.	95	6 (6.3)	N.A.	1.21 (0.39, 3.75) 0.7431	
HCV	27	2 (7.4)	N.A. (9.23, N.A.)	25	3 (12.0)	N.A. (14.42, N.A.)	0.87 (0.14, 5.22) 0.8782	
UNINFECTED	207	9 (4.3)	N.A.	205	16 (7.8)	N.A.	0.60 (0.27, 1.37) 0.2230	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2095
PRESENT	204	13 (6.4)	N.A.	199	14 (7.0)	N.A.	1.03 (0.48, 2.20) 0.9359	
ABSENT	128	4 (3.1)	N.A.	126	11 (8.7)	N.A.	0.41 (0.13, 1.30) 0.1171	
BASELINE ALPHA-- FETOPROTEIN								0.5288
< 400 NG/ML	224	9 (4.0)	N.A.	217	16 (7.4)	N.A.	0.64 (0.28, 1.44) 0.2765	
>= 400 NG/ML	108	8 (7.4)	N.A.	108	9 (8.3)	N.A.	0.91 (0.35, 2.38) 0.8467	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	6 (1.8)	N.A.	325	12 (3.7)	N.A.	0.56 (0.21, 1.49) 0.2376	0.3227
AGE < 65	162	2 (1.2)	N.A.	143	6 (4.2)	N.A.	0.32 (0.07, 1.61) 0.1472	
>= 65	170	4 (2.4)	N.A.	182	6 (3.3)	N.A.	0.84 (0.24, 2.98) 0.7819	
SEX								0.9921
MALE	269	6 (2.2)	N.A.	269	8 (3.0)	N.A.	0.89 (0.31, 2.56) 0.8243	
FEMALE	63	0	N.E.	56	4 (7.1)	N.A.	N.E. 0.0441	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7883
HBV	98	1 (1.0)	N.A.	95	4 (4.2)	N.A.	0.30 (0.03, 2.68) 0.2524	
HCV	27	1 (3.7)	N.A.	25	2 (8.0)	N.A. (14.42, N.A.)	0.62 (0.06, 6.82) 0.6909	
UNINFECTED	207	4 (1.9)	N.A.	205	6 (2.9)	N.A.	0.74 (0.21, 2.64) 0.6414	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4957
PRESENT	204	5 (2.5)	N.A.	199	8 (4.0)	N.A.	0.67 (0.22, 2.07) 0.4862	
ABSENT	128	1 (0.8)	N.A.	126	4 (3.2)	N.A.	0.29 (0.03, 2.60) 0.2398	
BASELINE ALPHA-- FETOPROTEIN								0.9897
< 400 NG/ML	224	6 (2.7)	N.A.	217	7 (3.2)	N.A.	0.99 (0.33, 2.94) 0.9815	
>= 400 NG/ML	108	0	N.E.	108	5 (4.6)	N.A.	N.E. 0.0092	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	14 (4.2)	N.A.	325	0	N.E.	N.E. <0.0001	
AGE								N.M.E.
< 65	162	8 (4.9)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	6 (3.5)	N.M.E.	182	0	N.E.	N.E.	
SEX								>0.9999
MALE	269	11 (4.1)	N.A.	269	0	N.E.	N.E. 0.0002	
FEMALE	63	3 (4.8)	N.A.	56	0	N.E.	N.E. 0.0763	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	3 (3.1)	N.A.	95	0	N.E.	N.E. 0.0477	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	11 (5.3)	N.A.	205	0	N.E.	N.E. 0.0003	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9995
PRESENT	204	12 (5.9)	N.A.	199	0	N.E.	N.E. 0.0001	
ABSENT	128	2 (1.6)	N.A.	126	0	N.E.	N.E. 0.1298	
BASELINE ALPHA-- FETOPROTEIN								0.9999
< 400 NG/ML	224	11 (4.9)	N.A.	217	0	N.E.	N.E. 0.0003	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	0	N.E.	N.E. 0.0430	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	9 (2.8)	N.A.	1.52 (0.65, 3.57) 0.3305	0.0355*
AGE < 65	162	10 (6.2)	N.A.	143	2 (1.4)	N.A.	4.55 (1.00, 20.81) 0.0320	
>= 65	170	3 (1.8)	N.A.	182	7 (3.8)	N.A.	0.50 (0.13, 1.95) 0.3087	
SEX								0.4821
MALE	269	10 (3.7)	N.A.	269	6 (2.2)	N.A.	1.94 (0.70, 5.33) 0.1933	
FEMALE	63	3 (4.8)	N.A.	56	3 (5.4)	N.A. (18.53, N.A.)	0.81 (0.16, 4.04) 0.7976	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9220
HBV	98	5 (5.1)	N.A.	95	4 (4.2)	N.A.	1.28 (0.34, 4.77) 0.7145	
HCV	27	2 (7.4)	N.A.	25	1 (4.0)	N.A.	2.58 (0.23, 28.56) 0.4232	
UNINFECTED	207	6 (2.9)	N.A.	205	4 (2.0)	N.A.	1.53 (0.43, 5.48) 0.5084	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5079
PRESENT	204	7 (3.4)	N.A.	199	6 (3.0)	N.A.	1.28 (0.43, 3.80) 0.6613	
ABSENT	128	6 (4.7)	N.A.	126	3 (2.4)	N.A.	2.07 (0.52, 8.31) 0.2947	
BASELINE ALPHA-- FETOPROTEIN								0.9290
< 400 NG/ML	224	7 (3.1)	N.A.	217	5 (2.3)	N.A.	1.41 (0.45, 4.48) 0.5533	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	4 (3.7)	N.A.	1.81 (0.51, 6.40) 0.3537	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	7 (2.2)	N.A.	2.09 (0.83, 5.24) 0.1096	0.6198
AGE < 65	162	5 (3.1)	N.A.	143	3 (2.1)	N.A.	1.74 (0.41, 7.27) 0.4442	
>= 65	170	8 (4.7)	N.A.	182	4 (2.2)	N.A.	2.44 (0.73, 8.14) 0.1330	
SEX								0.3981
MALE	269	11 (4.1)	N.A.	269	5 (1.9)	N.A.	2.54 (0.88, 7.34) 0.0733	
FEMALE	63	2 (3.2)	N.A.	56	2 (3.6)	N.A.	0.98 (0.14, 6.99) 0.9872	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8999
HBV	98	5 (5.1)	N.A.	95	3 (3.2)	N.A.	2.10 (0.50, 8.77) 0.3003	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A. (14.42, N.A.)	1.29 (0.08, 20.56) 0.8586	
UNINFECTED	207	7 (3.4)	N.A.	205	3 (1.5)	N.A.	2.53 (0.65, 9.80) 0.1655	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8472
PRESENT	204	9 (4.4)	N.A.	199	5 (2.5)	N.A.	1.90 (0.64, 5.70) 0.2421	
ABSENT	128	4 (3.1)	N.A.	126	2 (1.6)	N.A.	2.43 (0.45, 13.28) 0.2893	
BASELINE ALPHA-- FETOPROTEIN								0.5973
< 400 NG/ML	224	7 (3.1)	N.A.	217	3 (1.4)	N.A.	2.73 (0.71, 10.57) 0.1289	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	4 (3.7)	N.A.	1.43 (0.40, 5.16) 0.5841	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	11 (3.4)	N.A.	1.20 (0.53, 2.72) 0.6704	0.2097
AGE < 65	162	6 (3.7)	N.A.	143	2 (1.4)	N.A.	2.99 (0.60, 14.83) 0.1589	
>= 65	170	6 (3.5)	N.A.	182	9 (4.9)	N.A.	0.81 (0.29, 2.30) 0.6923	
SEX								0.4857
MALE	269	8 (3.0)	N.A.	269	9 (3.3)	N.A.	0.99 (0.38, 2.57) 0.9770	
FEMALE	63	4 (6.3)	N.A.	56	2 (3.6)	N.A.	2.06 (0.38, 11.24) 0.3952	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7813
HBV	98	3 (3.1)	N.A.	95	4 (4.2)	N.A.	0.87 (0.19, 3.90) 0.8577	
HCV	27	0	N.E.	25	1 (4.0)	N.A.	N.E. 0.4212	
UNINFECTED	207	9 (4.3)	N.A.	205	6 (2.9)	N.A.	1.57 (0.55, 4.44) 0.3947	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1602
PRESENT	204	10 (4.9)	N.A.	199	6 (3.0)	N.A.	1.87 (0.68, 5.15) 0.2204	
ABSENT	128	2 (1.6)	N.A.	126	5 (4.0)	N.A.	0.42 (0.08, 2.18) 0.2857	
BASELINE ALPHA-- FETOPROTEIN								0.7545
< 400 NG/ML	224	5 (2.2)	N.A.	217	4 (1.8)	N.A.	1.36 (0.37, 5.08) 0.6437	
>= 400 NG/ML	108	7 (6.5)	N.A.	108	7 (6.5)	N.A. (20.70, N.A.)	1.14 (0.39, 3.29) 0.8121	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A. (24.34, N.A.)	325	6 (1.8)	N.A.	2.35 (0.85, 6.51) 0.0906	N.M.E.
AGE < 65	162	5 (3.1)	N.M.E.	143	4 (2.8)	N.M.E.	N.M.E.	
>= 65	170	6 (3.5)	N.M.E.	182	2 (1.1)	N.M.E.	N.M.E.	
SEX								0.4060
MALE	269	9 (3.3)	N.A.	269	4 (1.5)	N.A.	2.63 (0.81, 8.55) 0.0951	
FEMALE	63	2 (3.2)	24.34 (N.A., N.A.)	56	2 (3.6)	N.A.	1.40 (0.18, 10.83) 0.7437	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9183
HBV	98	1 (1.0)	N.A.	95	1 (1.1)	N.A.	1.20 (0.08, 19.18) 0.8976	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	10 (4.8)	N.A. (24.34, N.A.)	205	5 (2.4)	N.A.	2.47 (0.83, 7.38) 0.0954	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	2 (1.0)	N.M.E.	199	6 (3.0)	N.M.E.	N.M.E.	
ABSENT	128	9 (7.0)	N.M.E.	126	0	N.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								0.8014
< 400 NG/ML	224	8 (3.6)	24.34 (24.34, N.A.)	217	4 (1.8)	N.A.	2.69 (0.78, 9.33) 0.1054	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	2 (1.9)	N.A.	1.75 (0.29, 10.53) 0.5372	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	12 (3.7)	N.A.	1.00 (0.44, 2.27) 0.9972	0.3843
AGE < 65	162	3 (1.9)	N.A.	143	1 (0.7)	N.A.	2.56 (0.26, 24.72) 0.4001	
>= 65	170	8 (4.7)	N.A.	182	11 (6.0)	N.A.	0.95 (0.38, 2.36) 0.9041	
SEX								0.1611
MALE	269	7 (2.6)	N.A.	269	11 (4.1)	N.A.	0.70 (0.27, 1.81) 0.4620	
FEMALE	63	4 (6.3)	N.A.	56	1 (1.8)	N.A.	3.89 (0.43, 34.77) 0.1905	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5909
HBV	98	2 (2.0)	N.A.	95	4 (4.2)	N.A.	0.56 (0.10, 3.04) 0.4921	
HCV	27	0	N.E.	25	2 (8.0)	N.A.	N.E. 0.1937	
UNINFECTED	207	9 (4.3)	N.A.	205	6 (2.9)	N.A.	1.60 (0.57, 4.50) 0.3720	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9855
PRESENT	204	5 (2.5)	N.A.	199	12 (6.0)	N.A.	0.44 (0.16, 1.26) 0.1158	
ABSENT	128	6 (4.7)	N.A.	126	0	N.E.	N.E. 0.0084	
BASELINE ALPHA-- FETOPROTEIN								0.0996
< 400 NG/ML	224	9 (4.0)	N.A.	217	6 (2.8)	N.A.	1.68 (0.60, 4.73) 0.3186	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	6 (5.6)	N.A.	0.33 (0.07, 1.69) 0.1652	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	4 (1.2)	N.A.	4.15 (1.16, 14.89) 0.0178	N.M.E.
AGE < 65	162	5 (3.1)	N.M.E.	143	3 (2.1)	N.M.E.	N.M.E.	
>= 65	170	6 (3.5)	N.M.E.	182	1 (0.5)	N.M.E.	N.M.E.	
SEX								0.0557
MALE	269	9 (3.3)	N.A.	269	1 (0.4)	N.A.	10.48 (1.33, 82.82) 0.0055	
FEMALE	63	2 (3.2)	N.A.	56	3 (5.4)	N.A. (24.80, N.A.)	1.03 (0.15, 7.35) 0.9737	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	4 (4.1)	N.M.E.	95	3 (3.2)	N.M.E.	N.M.E.	
HCV	27	2 (7.4)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	5 (2.4)	N.M.E.	205	1 (0.5)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9927
PRESENT	204	6 (2.9)	N.A.	199	4 (2.0)	N.A.	2.23 (0.56, 8.93) 0.2456	
ABSENT	128	5 (3.9)	N.A.	126	0	N.E.	N.E. 0.0155	
BASELINE ALPHA-- FETOPROTEIN								N.M.E.
< 400 NG/ML	224	7 (3.1)	N.M.E.	217	2 (0.9)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	4 (3.7)	N.M.E.	108	2 (1.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	N.A.	325	5 (1.5)	N.A.	2.01 (0.68, 5.92) 0.1953	
AGE								N.M.E.
< 65	162	5 (3.1)	N.M.E.	143	2 (1.4)	N.M.E.	N.M.E.	
>= 65	170	5 (2.9)	N.M.E.	182	3 (1.6)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	269	5 (1.9)	N.M.E.	269	3 (1.1)	N.M.E.	N.M.E.	
FEMALE	63	5 (7.9)	N.M.E.	56	2 (3.6)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9980
HBV	98	2 (2.0)	N.A.	95	1 (1.1)	N.A.	2.35 (0.21, 25.98) 0.4722	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	8 (3.9)	N.A.	205	4 (2.0)	N.A.	1.93 (0.57, 6.46) 0.2802	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	7 (3.4)	N.M.E.	199	2 (1.0)	N.M.E.	N.M.E.	
ABSENT	128	3 (2.3)	N.M.E.	126	3 (2.4)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								0.1278
< 400 NG/ML	224	8 (3.6)	N.A.	217	2 (0.9)	N.A.	4.28 (0.91, 20.18) 0.0449	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	3 (2.8)	N.A. (20.53, N.A.)	0.51 (0.08, 3.23) 0.4703	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	5 (1.5)	N.A.	325	10 (3.1)	N.A.	0.54 (0.19, 1.60) 0.2601	0.8932
AGE < 65	162	2 (1.2)	N.A.	143	3 (2.1)	N.A.	0.63 (0.11, 3.77) 0.6101	
>= 65	170	3 (1.8)	N.A.	182	7 (3.8)	N.A.	0.53 (0.14, 2.07) 0.3540	
SEX								N.M.E.
MALE	269	4 (1.5)	N.M.E.	269	5 (1.9)	N.M.E.	N.M.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	5 (8.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8923
HBV	98	0	N.E.	95	2 (2.1)	N.A.	N.E. 0.1725	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A.	1.21 (0.08, 19.38)	
UNINFECTED	207	4 (1.9)	N.A.	205	7 (3.4)	N.A.	0.59 (0.17, 2.02)	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	2 (1.0)	N.M.E.	199	5 (2.5)	N.M.E.	N.M.E.	
ABSENT	128	3 (2.3)	N.M.E.	126	5 (4.0)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								0.9777
< 400 NG/ML	224	4 (1.8)	N.A.	217	8 (3.7)	N.A.	0.54 (0.16, 1.80) 0.3098	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	2 (1.9)	N.A.	0.53 (0.05, 5.94) 0.6045	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	51 (15.4)	24.51 (N.A., N.A.)	325	75 (23.1)	N.A. (18.23, N.A.)	0.74 (0.51, 1.06) 0.0959	0.7797
AGE < 65	162	29 (17.9)	N.A.	143	35 (24.5)	N.A. (17.58, N.A.)	0.76 (0.46, 1.24) 0.2651	
>= 65	170	22 (12.9)	24.51 (N.A., N.A.)	182	40 (22.0)	N.A. (18.07, N.A.)	0.70 (0.41, 1.19) 0.1817	
SEX								0.6834
MALE	269	45 (16.7)	24.51 (N.A., N.A.)	269	65 (24.2)	26.97 (18.07, N.A.)	0.76 (0.52, 1.12) 0.1705	
FEMALE	63	6 (9.5)	N.A.	56	10 (17.9)	N.A.	0.60 (0.21, 1.66) 0.3174	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0179*
HBV	98	20 (20.4)	N.A. (20.93, N.A.)	95	21 (22.1)	N.A. (16.39, N.A.)	1.07 (0.58, 1.97) 0.8345	
HCV	27	6 (22.2)	N.A. (10.51, N.A.)	25	2 (8.0)	N.A.	3.39 (0.67, 17.04) 0.1162	
UNINFECTED	207	25 (12.1)	24.51 (N.A., N.A.)	205	52 (25.4)	26.97 (15.77, N.A.)	0.51 (0.31, 0.82) 0.0052	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2894
PRESENT	204	33 (16.2)	N.A.	199	54 (27.1)	18.23 (15.61, N.A.)	0.64 (0.41, 0.99) 0.0443	
ABSENT	128	18 (14.1)	24.51 (N.A., N.A.)	126	21 (16.7)	N.A. (20.24, N.A.)	0.99 (0.52, 1.87) 0.9759	
BASELINE ALPHA-- FETOPROTEIN								0.1209
< 400 NG/ML	224	32 (14.3)	24.51 (N.A., N.A.)	217	38 (17.5)	N.A.	0.90 (0.56, 1.44) 0.6542	
>= 400 NG/ML	108	19 (17.6)	N.A.	108	37 (34.3)	15.24 (9.43, 26.97)	0.57 (0.33, 1.00) 0.0492	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	44 (13.3)	24.51 (N.A., N.A.)	325	67 (20.6)	N.A. (26.97, N.A.)	0.72 (0.49, 1.06) 0.0969	0.5783
AGE < 65	162	25 (15.4)	N.A.	143	29 (20.3)	N.A.	0.79 (0.46, 1.35) 0.3822	
>= 65	170	19 (11.2)	24.51 (N.A., N.A.)	182	38 (20.9)	N.A. (19.15, N.A.)	0.66 (0.38, 1.15) 0.1362	
SEX								0.8537
MALE	269	38 (14.1)	24.51 (N.A., N.A.)	269	58 (21.6)	N.A. (19.15, N.A.)	0.75 (0.49, 1.13) 0.1681	
FEMALE	63	6 (9.5)	N.A. (20.93, N.A.)	56	9 (16.1)	N.A.	0.61 (0.21, 1.74) 0.3490	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0526
HBV	98	16 (16.3)	N.A.	95	18 (18.9)	N.A. (18.07, N.A.)	0.99 (0.51, 1.95) 0.9837	
HCV	27	5 (18.5)	N.A. (10.51, N.A.)	25	2 (8.0)	N.A.	3.14 (0.61, 16.23) 0.1488	
UNINFECTED	207	23 (11.1)	24.51 (N.A., N.A.)	205	47 (22.9)	N.A. (17.58, N.A.)	0.52 (0.32, 0.87) 0.0108	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps). PT: Malignant Neoplasm Progression

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3925
PRESENT	204	29 (14.2)	N.A.	199	48 (24.1)	N.A. (16.39, N.A.)	0.64 (0.40, 1.02) 0.0610	
ABSENT	128	15 (11.7)	24.51 (N.A., N.A.)	126	19 (15.1)	N.A.	0.93 (0.47, 1.85) 0.8395	
BASELINE ALPHA-- FETOPROTEIN								0.1845
< 400 NG/ML	224	26 (11.6)	24.51 (N.A., N.A.)	217	32 (14.7)	N.A.	0.88 (0.52, 1.49) 0.6318	
>= 400 NG/ML	108	18 (16.7)	N.A.	108	35 (32.4)	15.61 (9.43, N.A.)	0.57 (0.32, 1.02) 0.0558	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	50 (15.1)	N.A.	325	40 (12.3)	N.A.	1.36 (0.89, 2.08) 0.1471	0.9954
AGE								
< 65	162	27 (16.7)	N.A.	143	19 (13.3)	N.A.	1.30 (0.72, 2.34) 0.3850	
>= 65	170	23 (13.5)	N.A.	182	21 (11.5)	N.A.	1.39 (0.76, 2.55) 0.2761	0.7193
SEX								
MALE	269	37 (13.8)	N.A.	269	32 (11.9)	N.A.	1.29 (0.79, 2.08) 0.3045	
FEMALE	63	13 (20.6)	N.A. (10.48, N.A.)	56	8 (14.3)	N.A.	1.54 (0.64, 3.73) 0.3304	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4086
HBV	98	16 (16.3)	N.A. (19.19, N.A.)	95	11 (11.6)	N.A. (19.42, N.A.)	1.67 (0.77, 3.61) 0.1870	
HCV	27	1 (3.7)	N.A.	25	3 (12.0)	N.A.	0.34 (0.04, 3.24) 0.3250	
UNINFECTED	207	33 (15.9)	N.A.	205	26 (12.7)	N.A.	1.41 (0.84, 2.38) 0.1927	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Gastrointestinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4120
PRESENT	204	33 (16.2)	N.A.	199	23 (11.6)	N.A. (26.15, N.A.)	1.61 (0.94, 2.77) 0.0810	
ABSENT	128	17 (13.3)	N.A.	126	17 (13.5)	N.A.	1.05 (0.53, 2.06) 0.8908	
BASELINE ALPHA-- FETOPROTEIN								0.4288
< 400 NG/ML	224	33 (14.7)	N.A.	217	23 (10.6)	N.A.	1.48 (0.87, 2.53) 0.1452	
>= 400 NG/ML	108	17 (15.7)	N.A.	108	17 (15.7)	N.A. (15.21, N.A.)	1.15 (0.58, 2.30) 0.6819	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	48 (14.5)	N.A.	325	33 (10.2)	N.A.	1.58 (1.01, 2.48) 0.0436	0.0896
AGE								
< 65	162	14 (8.6)	N.A.	143	14 (9.8)	N.A.	0.96 (0.45, 2.05) 0.9108	
>= 65	170	34 (20.0)	N.A.	182	19 (10.4)	(30.32, N.A.) N.A.	2.15 (1.23, 3.78) 0.0063	0.6396
SEX								
MALE	269	40 (14.9)	N.A.	269	27 (10.0)	N.A.	1.69 (1.03, 2.78) 0.0353	
FEMALE	63	8 (12.7)	N.A. (20.50, N.A.)	56	6 (10.7)	N.A. (18.73, N.A.)	1.15 (0.39, 3.34) 0.8018	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4964
HBV	98	9 (9.2)	N.A.	95	7 (7.4)	N.A.	1.43 (0.53, 3.85) 0.4725	
HCV	27	5 (18.5)	N.A. (6.64, N.A.)	25	7 (28.0)	N.A. (6.57, N.A.)	0.81 (0.26, 2.56) 0.7223	
UNINFECTED	207	34 (16.4)	N.A.	205	19 (9.3)	N.A. (30.32, N.A.)	1.89 (1.06, 3.36) 0.0277	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Infections and Infestations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3196
PRESENT	204	29 (14.2)	N.A.	199	23 (11.6)	N.A. (30.32, N.A.)	1.32 (0.75, 2.30) 0.3349	
ABSENT	128	19 (14.8)	N.A.	126	10 (7.9)	N.A.	2.14 (0.99, 4.61) 0.0461	
BASELINE ALPHA-- FETOPROTEIN								0.0288*
< 400 NG/ML	224	32 (14.3)	N.A.	217	14 (6.5)	N.A.	2.41 (1.29, 4.53) 0.0046	
>= 400 NG/ML	108	16 (14.8)	N.A.	108	19 (17.6)	30.32 (14.42, N.A.)	0.88 (0.45, 1.75) 0.7240	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	41 (12.3)	N.A.	325	21 (6.5)	N.A. (36.93, N.A.)	2.27 (1.33, 3.88) 0.0020	0.3402
AGE < 65	162	19 (11.7)	N.A.	143	11 (7.7)	N.A. (36.93, N.A.)	1.77 (0.82, 3.81) 0.1401	
>= 65	170	22 (12.9)	N.A.	182	10 (5.5)	N.A.	2.81 (1.33, 5.93) 0.0049	
SEX								0.5153
MALE	269	33 (12.3)	N.A.	269	16 (5.9)	N.A. (36.93, N.A.)	2.48 (1.34, 4.57) 0.0026	
FEMALE	63	8 (12.7)	N.A.	56	5 (8.9)	N.A.	1.60 (0.52, 4.88) 0.4097	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9920
HBV	98	9 (9.2)	N.A.	95	5 (5.3)	36.93 (N.A., N.A.)	2.60 (0.80, 8.44) 0.0997	
HCV	27	4 (14.8)	N.A. (16.10, N.A.)	25	0	N.E.	N.E. 0.0446	
UNINFECTED	207	28 (13.5)	N.A.	205	16 (7.8)	N.A.	1.89 (1.02, 3.51) 0.0394	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Hepatobiliary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9186
PRESENT	204	26 (12.7)	N.A.	199	13 (6.5)	36.93 (36.93, N.A.)	2.28 (1.15, 4.54) 0.0152	
ABSENT	128	15 (11.7)	N.A.	126	8 (6.3)	N.A.	2.23 (0.95, 5.27) 0.0602	
BASELINE ALPHA-- FETOPROTEIN								0.4532
< 400 NG/ML	224	23 (10.3)	N.A.	217	14 (6.5)	N.A. (36.93, N.A.)	1.96 (0.99, 3.87) 0.0486	
>= 400 NG/ML	108	18 (16.7)	N.A.	108	7 (6.5)	N.A.	2.90 (1.21, 6.99) 0.0129	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	18 (5.4)	25.26 (N.A., N.A.)	325	20 (6.2)	N.A.	1.09 (0.57, 2.10) 0.7871	0.0914
AGE < 65	162	2 (1.2)	N.A.	143	6 (4.2)	N.A.	0.27 (0.05, 1.36) 0.0890	
>= 65	170	16 (9.4)	25.26 (N.A., N.A.)	182	14 (7.7)	N.A. (30.23, N.A.)	1.74 (0.83, 3.66) 0.1386	
SEX								0.7125
MALE	269	13 (4.8)	25.26 (N.A., N.A.)	269	14 (5.2)	N.A.	1.26 (0.58, 2.75) 0.5661	
FEMALE	63	5 (7.9)	N.A.	56	6 (10.7)	N.A. (18.86, N.A.)	0.76 (0.23, 2.50) 0.6533	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5197
HBV	98	2 (2.0)	N.A.	95	4 (4.2)	N.A.	0.51 (0.09, 2.79) 0.4275	
HCV	27	1 (3.7)	N.A.	25	3 (12.0)	N.A. (11.83, N.A.)	0.45 (0.05, 4.33) 0.4750	
UNINFECTED	207	15 (7.2)	25.26 (N.A., N.A.)	205	13 (6.3)	N.A. (30.23, N.A.)	1.50 (0.69, 3.25) 0.3019	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Nervous System Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9937
PRESENT	204	12 (5.9)	25.26 (N.A., N.A.)	199	13 (6.5)	N.A.	1.07 (0.48, 2.38) 0.8655	
ABSENT	128	6 (4.7)	N.A.	126	7 (5.6)	N.A. (30.23, N.A.)	1.11 (0.36, 3.45) 0.8561	
BASELINE ALPHA-- FETOPROTEIN								0.8370
< 400 NG/ML	224	13 (5.8)	25.26 (N.A., N.A.)	217	15 (6.9)	N.A.	1.08 (0.50, 2.33) 0.8447	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	5 (4.6)	N.A.	1.04 (0.29, 3.67) 0.9531	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	17 (5.1)	N.A.	325	25 (7.7)	N.A.	0.76 (0.41, 1.41) 0.3814	0.4743
AGE < 65	162	7 (4.3)	N.A.	143	6 (4.2)	N.A.	1.16 (0.39, 3.45) 0.7901	
>= 65	170	10 (5.9)	N.A.	182	19 (10.4)	N.A.	0.67 (0.31, 1.44) 0.2994	
SEX								0.1164
MALE	269	16 (5.9)	N.A.	269	19 (7.1)	N.A.	0.98 (0.50, 1.90) 0.9430	
FEMALE	63	1 (1.6)	N.A.	56	6 (10.7)	N.A.	0.16 (0.02, 1.36) 0.0562	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6179
HBV	98	6 (6.1)	N.A.	95	6 (6.3)	N.A.	1.21 (0.39, 3.75) 0.7431	
HCV	27	2 (7.4)	N.A. (9.23, N.A.)	25	3 (12.0)	N.A. (14.42, N.A.)	0.87 (0.14, 5.22) 0.8782	
UNINFECTED	207	9 (4.3)	N.A.	205	16 (7.8)	N.A.	0.60 (0.27, 1.37) 0.2230	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2095
PRESENT	204	13 (6.4)	N.A.	199	14 (7.0)	N.A.	1.03 (0.48, 2.20) 0.9359	
ABSENT	128	4 (3.1)	N.A.	126	11 (8.7)	N.A.	0.41 (0.13, 1.30) 0.1171	
BASELINE ALPHA-- FETOPROTEIN								0.5288
< 400 NG/ML	224	9 (4.0)	N.A.	217	16 (7.4)	N.A.	0.64 (0.28, 1.44) 0.2765	
>= 400 NG/ML	108	8 (7.4)	N.A.	108	9 (8.3)	N.A.	0.91 (0.35, 2.38) 0.8467	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	6 (1.8)	N.A.	325	12 (3.7)	N.A.	0.56 (0.21, 1.49) 0.2376	0.3227
AGE < 65	162	2 (1.2)	N.A.	143	6 (4.2)	N.A.	0.32 (0.07, 1.61) 0.1472	
>= 65	170	4 (2.4)	N.A.	182	6 (3.3)	N.A.	0.84 (0.24, 2.98) 0.7819	
SEX								0.9921
MALE	269	6 (2.2)	N.A.	269	8 (3.0)	N.A.	0.89 (0.31, 2.56) 0.8243	
FEMALE	63	0	N.E.	56	4 (7.1)	N.A.	N.E. 0.0441	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7883
HBV	98	1 (1.0)	N.A.	95	4 (4.2)	N.A.	0.30 (0.03, 2.68) 0.2524	
HCV	27	1 (3.7)	N.A.	25	2 (8.0)	N.A. (14.42, N.A.)	0.62 (0.06, 6.82) 0.6909	
UNINFECTED	207	4 (1.9)	N.A.	205	6 (2.9)	N.A.	0.74 (0.21, 2.64) 0.6414	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: General Disorders and Administration Site Conditions. PT: Pyrexia

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.4957
PRESENT	204	5 (2.5)	N.A.	199	8 (4.0)	N.A.	0.67 (0.22, 2.07) 0.4862	
ABSENT	128	1 (0.8)	N.A.	126	4 (3.2)	N.A.	0.29 (0.03, 2.60) 0.2398	
BASELINE ALPHA-- FETOPROTEIN								0.9897
< 400 NG/ML	224	6 (2.7)	N.A.	217	7 (3.2)	N.A.	0.99 (0.33, 2.94) 0.9815	
>= 400 NG/ML	108	0	N.E.	108	5 (4.6)	N.A.	N.E. 0.0092	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	14 (4.2)	N.A.	325	0	N.E.	N.E. <0.0001	N.M.E. >0.9999
AGE								
< 65	162	8 (4.9)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	6 (3.5)	N.M.E.	182	0	N.E.	N.E.	
SEX								
MALE	269	11 (4.1)	N.A.	269	0	N.E.	N.E. 0.0002	
FEMALE	63	3 (4.8)	N.A.	56	0	N.E.	N.E. 0.0763	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								>0.9999
HBV	98	3 (3.1)	N.A.	95	0	N.E.	N.E. 0.0477	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	11 (5.3)	N.A.	205	0	N.E.	N.E. 0.0003	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Endocrine Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9995
PRESENT	204	12 (5.9)	N.A.	199	0	N.E.	N.E. 0.0001	
ABSENT	128	2 (1.6)	N.A.	126	0	N.E.	N.E. 0.1298	
BASELINE ALPHA-- FETOPROTEIN								0.9999
< 400 NG/ML	224	11 (4.9)	N.A.	217	0	N.E.	N.E. 0.0003	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	0	N.E.	N.E. 0.0430	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	9 (2.8)	N.A.	1.52 (0.65, 3.57) 0.3305	0.0355*
AGE < 65	162	10 (6.2)	N.A.	143	2 (1.4)	N.A.	4.55 (1.00, 20.81) 0.0320	
>= 65	170	3 (1.8)	N.A.	182	7 (3.8)	N.A.	0.50 (0.13, 1.95) 0.3087	
SEX								0.4821
MALE	269	10 (3.7)	N.A.	269	6 (2.2)	N.A.	1.94 (0.70, 5.33) 0.1933	
FEMALE	63	3 (4.8)	N.A.	56	3 (5.4)	N.A. (18.53, N.A.)	0.81 (0.16, 4.04) 0.7976	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9220
HBV	98	5 (5.1)	N.A.	95	4 (4.2)	N.A.	1.28 (0.34, 4.77) 0.7145	
HCV	27	2 (7.4)	N.A.	25	1 (4.0)	N.A.	2.58 (0.23, 28.56) 0.4232	
UNINFECTED	207	6 (2.9)	N.A.	205	4 (2.0)	N.A.	1.53 (0.43, 5.48) 0.5084	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Investigations

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5079
PRESENT	204	7 (3.4)	N.A.	199	6 (3.0)	N.A.	1.28 (0.43, 3.80) 0.6613	
ABSENT	128	6 (4.7)	N.A.	126	3 (2.4)	N.A.	2.07 (0.52, 8.31) 0.2947	
BASELINE ALPHA-- FETOPROTEIN								0.9290
< 400 NG/ML	224	7 (3.1)	N.A.	217	5 (2.3)	N.A.	1.41 (0.45, 4.48) 0.5533	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	4 (3.7)	N.A.	1.81 (0.51, 6.40) 0.3537	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	13 (3.9)	N.A.	325	7 (2.2)	N.A.	2.09 (0.83, 5.24) 0.1096	0.6198
AGE < 65	162	5 (3.1)	N.A.	143	3 (2.1)	N.A.	1.74 (0.41, 7.27) 0.4442	
>= 65	170	8 (4.7)	N.A.	182	4 (2.2)	N.A.	2.44 (0.73, 8.14) 0.1330	
SEX								0.3981
MALE	269	11 (4.1)	N.A.	269	5 (1.9)	N.A.	2.54 (0.88, 7.34) 0.0733	
FEMALE	63	2 (3.2)	N.A.	56	2 (3.6)	N.A.	0.98 (0.14, 6.99) 0.9872	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8999
HBV	98	5 (5.1)	N.A.	95	3 (3.2)	N.A.	2.10 (0.50, 8.77) 0.3003	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A. (14.42, N.A.)	1.29 (0.08, 20.56) 0.8586	
UNINFECTED	207	7 (3.4)	N.A.	205	3 (1.5)	N.A.	2.53 (0.65, 9.80) 0.1655	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Respiratory, Thoracic and Mediastinal Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8472
PRESENT	204	9 (4.4)	N.A.	199	5 (2.5)	N.A.	1.90 (0.64, 5.70) 0.2421	
ABSENT	128	4 (3.1)	N.A.	126	2 (1.6)	N.A.	2.43 (0.45, 13.28) 0.2893	
BASELINE ALPHA-- FETOPROTEIN								0.5973
< 400 NG/ML	224	7 (3.1)	N.A.	217	3 (1.4)	N.A.	2.73 (0.71, 10.57) 0.1289	
>= 400 NG/ML	108	6 (5.6)	N.A.	108	4 (3.7)	N.A.	1.43 (0.40, 5.16) 0.5841	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	12 (3.6)	N.A.	325	11 (3.4)	N.A.	1.20 (0.53, 2.72) 0.6704	0.2097
AGE < 65	162	6 (3.7)	N.A.	143	2 (1.4)	N.A.	2.99 (0.60, 14.83) 0.1589	
>= 65	170	6 (3.5)	N.A.	182	9 (4.9)	N.A.	0.81 (0.29, 2.30) 0.6923	
SEX								0.4857
MALE	269	8 (3.0)	N.A.	269	9 (3.3)	N.A.	0.99 (0.38, 2.57) 0.9770	
FEMALE	63	4 (6.3)	N.A.	56	2 (3.6)	N.A.	2.06 (0.38, 11.24) 0.3952	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.7813
HBV	98	3 (3.1)	N.A.	95	4 (4.2)	N.A.	0.87 (0.19, 3.90) 0.8577	
HCV	27	0	N.E.	25	1 (4.0)	N.A.	N.E. 0.4212	
UNINFECTED	207	9 (4.3)	N.A.	205	6 (2.9)	N.A.	1.57 (0.55, 4.44) 0.3947	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Metabolism and Nutrition Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1602
PRESENT	204	10 (4.9)	N.A.	199	6 (3.0)	N.A.	1.87 (0.68, 5.15) 0.2204	
ABSENT	128	2 (1.6)	N.A.	126	5 (4.0)	N.A.	0.42 (0.08, 2.18) 0.2857	
BASELINE ALPHA-- FETOPROTEIN								0.7545
< 400 NG/ML	224	5 (2.2)	N.A.	217	4 (1.8)	N.A.	1.36 (0.37, 5.08) 0.6437	
>= 400 NG/ML	108	7 (6.5)	N.A.	108	7 (6.5)	N.A. (20.70, N.A.)	1.14 (0.39, 3.29) 0.8121	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A. (24.34, N.A.)	325	6 (1.8)	N.A.	2.35 (0.85, 6.51) 0.0906	N.M.E.
AGE < 65	162	5 (3.1)	N.M.E.	143	4 (2.8)	N.M.E.	N.M.E.	
>= 65	170	6 (3.5)	N.M.E.	182	2 (1.1)	N.M.E.	N.M.E.	
SEX								0.4060
MALE	269	9 (3.3)	N.A.	269	4 (1.5)	N.A.	2.63 (0.81, 8.55) 0.0951	
FEMALE	63	2 (3.2)	24.34 (N.A., N.A.)	56	2 (3.6)	N.A.	1.40 (0.18, 10.83) 0.7437	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9183
HBV	98	1 (1.0)	N.A.	95	1 (1.1)	N.A.	1.20 (0.08, 19.18) 0.8976	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	10 (4.8)	N.A. (24.34, N.A.)	205	5 (2.4)	N.A.	2.47 (0.83, 7.38) 0.0954	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Injury, Poisoning and Procedural Complications

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	2 (1.0)	N.M.E.	199	6 (3.0)	N.M.E.	N.M.E.	
ABSENT	128	9 (7.0)	N.M.E.	126	0	N.E.	N.E.	
BASELINE ALPHA-- FETOPROTEIN								0.8014
< 400 NG/ML	224	8 (3.6)	24.34 (24.34, N.A.)	217	4 (1.8)	N.A.	2.69 (0.78, 9.33) 0.1054	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	2 (1.9)	N.A.	1.75 (0.29, 10.53) 0.5372	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	12 (3.7)	N.A.	1.00 (0.44, 2.27) 0.9972	0.3843
AGE < 65	162	3 (1.9)	N.A.	143	1 (0.7)	N.A.	2.56 (0.26, 24.72) 0.4001	
>= 65	170	8 (4.7)	N.A.	182	11 (6.0)	N.A.	0.95 (0.38, 2.36) 0.9041	
SEX								0.1611
MALE	269	7 (2.6)	N.A.	269	11 (4.1)	N.A.	0.70 (0.27, 1.81) 0.4620	
FEMALE	63	4 (6.3)	N.A.	56	1 (1.8)	N.A.	3.89 (0.43, 34.77) 0.1905	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.5909
HBV	98	2 (2.0)	N.A.	95	4 (4.2)	N.A.	0.56 (0.10, 3.04) 0.4921	
HCV	27	0	N.E.	25	2 (8.0)	N.A.	N.E. 0.1937	
UNINFECTED	207	9 (4.3)	N.A.	205	6 (2.9)	N.A.	1.60 (0.57, 4.50) 0.3720	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Renal and Urinary Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9855
PRESENT	204	5 (2.5)	N.A.	199	12 (6.0)	N.A.	0.44 (0.16, 1.26) 0.1158	
ABSENT	128	6 (4.7)	N.A.	126	0	N.E.	N.E. 0.0084	
BASELINE ALPHA-- FETOPROTEIN								0.0996
< 400 NG/ML	224	9 (4.0)	N.A.	217	6 (2.8)	N.A.	1.68 (0.60, 4.73) 0.3186	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	6 (5.6)	N.A.	0.33 (0.07, 1.69) 0.1652	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	11 (3.3)	N.A.	325	4 (1.2)	N.A.	4.15 (1.16, 14.89) 0.0178	N.M.E.
AGE < 65	162	5 (3.1)	N.M.E.	143	3 (2.1)	N.M.E.	N.M.E.	
>= 65	170	6 (3.5)	N.M.E.	182	1 (0.5)	N.M.E.	N.M.E.	
SEX								0.0557
MALE	269	9 (3.3)	N.A.	269	1 (0.4)	N.A.	10.48 (1.33, 82.82) 0.0055	
FEMALE	63	2 (3.2)	N.A.	56	3 (5.4)	N.A. (24.80, N.A.)	1.03 (0.15, 7.35) 0.9737	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	4 (4.1)	N.M.E.	95	3 (3.2)	N.M.E.	N.M.E.	
HCV	27	2 (7.4)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	5 (2.4)	N.M.E.	205	1 (0.5)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects
SOC: Skin and Subcutaneous Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9927
PRESENT	204	6 (2.9)	N.A.	199	4 (2.0)	N.A.	2.23 (0.56, 8.93) 0.2456	
ABSENT	128	5 (3.9)	N.A.	126	0	N.E.	N.E. 0.0155	
BASELINE ALPHA-- FETOPROTEIN								N.M.E.
< 400 NG/ML	224	7 (3.1)	N.M.E.	217	2 (0.9)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	4 (3.7)	N.M.E.	108	2 (1.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	10 (3.0)	N.A.	325	5 (1.5)	N.A.	2.01 (0.68, 5.92) 0.1953	
AGE								N.M.E.
< 65	162	5 (3.1)	N.M.E.	143	2 (1.4)	N.M.E.	N.M.E.	
>= 65	170	5 (2.9)	N.M.E.	182	3 (1.6)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	269	5 (1.9)	N.M.E.	269	3 (1.1)	N.M.E.	N.M.E.	
FEMALE	63	5 (7.9)	N.M.E.	56	2 (3.6)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9980
HBV	98	2 (2.0)	N.A.	95	1 (1.1)	N.A.	2.35 (0.21, 25.98) 0.4722	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	8 (3.9)	N.A.	205	4 (2.0)	N.A.	1.93 (0.57, 6.46) 0.2802	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-ebr2618.sas

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Musculoskeletal and Connective Tissue Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	7 (3.4)	N.M.E.	199	2 (1.0)	N.M.E.	N.M.E.	
ABSENT	128	3 (2.3)	N.M.E.	126	3 (2.4)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								0.1278
< 400 NG/ML	224	8 (3.6)	N.A.	217	2 (0.9)	N.A.	4.28 (0.91, 20.18) 0.0449	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	3 (2.8)	N.A. (20.53, N.A.)	0.51 (0.08, 3.23) 0.4703	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
OVERALL	332	5 (1.5)	N.A.	325	10 (3.1)	N.A.	0.54 (0.19, 1.60) 0.2601	0.8932
AGE < 65	162	2 (1.2)	N.A.	143	3 (2.1)	N.A.	0.63 (0.11, 3.77) 0.6101	
>= 65	170	3 (1.8)	N.A.	182	7 (3.8)	N.A.	0.53 (0.14, 2.07) 0.3540	
SEX								N.M.E.
MALE	269	4 (1.5)	N.M.E.	269	5 (1.9)	N.M.E.	N.M.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	5 (8.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteteae-sub-eb2618.sas

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8923
HBV	98	0	N.E.	95	2 (2.1)	N.A.	N.E. 0.1725	
HCV	27	1 (3.7)	N.A.	25	1 (4.0)	N.A.	1.21 (0.08, 19.38)	
UNINFECTED	207	4 (1.9)	N.A.	205	7 (3.4)	N.A.	0.59 (0.17, 2.02)	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 12.3
Time to Event Analyses for Serious TEAE
By Significant Subgroup and SOC/PT
All Treated Subjects

SOC: Vascular Disorders

Subgroups	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) p-value (2)(3)	Test for Interaction P-value (4)(5)
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	2 (1.0)	N.M.E.	199	5 (2.5)	N.M.E.	N.M.E.	
ABSENT	128	3 (2.3)	N.M.E.	126	5 (4.0)	N.M.E.	N.M.E.	
BASELINE ALPHA-- FETOPROTEIN								0.9777
< 400 NG/ML	224	4 (1.8)	N.A.	217	8 (3.7)	N.A.	0.54 (0.16, 1.80) 0.3098	
>= 400 NG/ML	108	1 (0.9)	N.A.	108	2 (1.9)	N.A.	0.53 (0.05, 5.94) 0.6045	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY IMMUNE-MEDIATED ADVERSE EVENT (IMAE)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	191 (57.5)	2.83 (2.17, 4.30)	325	14 (4.3)	N.A.	20.69 (12.00, 35.67) <0.0001	
AGE								0.1543
< 65	162	93 (57.4)	3.61 (2.17, 6.24)	143	3 (2.1)	N.A.	41.17 (13.02, >99.99) <0.0001	
>= 65	170	98 (57.6)	2.63 (2.07, 4.11)	182	11 (6.0)	N.A.	15.08 (8.06, 28.22) <0.0001	
SEX								0.3532
MALE	269	146 (54.3)	3.71 (2.46, 6.47)	269	9 (3.3)	N.A.	24.21 (12.33, 47.53) <0.0001	
FEMALE	63	45 (71.4)	2.10 (1.38, 2.79)	56	5 (8.9)	N.A.	15.22 (5.95, 38.95) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY IMMUNE-MEDIATED ADVERSE EVENT (IMAE)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9604
HBV	98	47 (48.0)	12.71 (2.17, N.A.)	95	4 (4.2)	N.A.	16.38 (5.88, 45.60) <0.0001	
HCV	27	16 (59.3)	2.79 (1.35, N.A.)	25	0	N.E.	N.E.	
UNINFECTED	207	128 (61.8)	2.53 (2.10, 3.38)	205	10 (4.9)	N.A.	20.09 (10.53, 38.33) <0.0001	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2559
PRESENT	204	122 (59.8)	2.63 (2.07, 3.68)	199	7 (3.5)	N.A.	26.80 (12.48, 57.53) <0.0001	
ABSENT	128	69 (53.9)	4.86 (2.10, 20.44)	126	7 (5.6)	N.A.	14.60 (6.69, 31.86) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY IMMUNE-MEDIATED ADVERSE EVENT (IMAE)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.2084
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	137 (61.2)	2.76 (2.07, 3.71)	217	8 (3.7)	N.A.	26.32 (12.88, 53.81) <0.0001	
>= 400 NG/ML	108	54 (50.0)	6.24 (2.17, N.A.)	108	6 (5.6)	N.A.	13.01 (5.58, 30.32) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PNEUMONITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	7 (2.1)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	5 (3.1)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	2 (1.2)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	5 (1.9)	N.M.E.	269	0	N.E.	N.E.	
FEMALE	63	2 (3.2)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PNEUMONITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	4 (4.1)	N.M.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	3 (1.4)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	5 (2.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	2 (1.6)	N.M.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PNEUMONITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	6 (2.7)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	1 (0.9)	N.M.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DIARRHEA/COLITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	28 (8.4)	N.A.	325	1 (0.3)	N.A.	29.24 (3.98, >99.99) <0.0001	
AGE								0.9880
< 65	162	14 (8.6)	N.A.	143	0	N.E.	N.E.	
>= 65	170	14 (8.2)	N.A.	182	1 (0.5)	N.A.	16.47 (2.17, >99.99) 0.0002	
SEX								0.9880
MALE	269	18 (6.7)	N.A.	269	0	N.E.	N.E.	
FEMALE	63	10 (15.9)	N.A.	56	1 (1.8)	N.A.	9.47 (1.21, 73.97) 0.0087	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DIARRHEA/COLITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9999
HBV	98	3 (3.1)	N.A.	95	0	N.E.	N.E.	
HCV	27	2 (7.4)	N.A.	25	0	N.E.	N.E.	
UNINFECTED	207	23 (11.1)	N.A.	205	1 (0.5)	N.A.	24.51 (3.31, >99.99) <0.0001	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9886
PRESENT	204	16 (7.8)	N.A.	199	1 (0.5)	N.A.	16.65 (2.21, >99.99) 0.0002	
ABSENT	128	12 (9.4)	N.A.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DIARRHEA/COLITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.9850
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	25 (11.2)	N.A.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	1 (0.9)	N.A.	3.21 (0.33, 30.88) 0.2855	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HEPATITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	63 (19.0)	N.A.	325	0	N.E.	N.E.	
AGE								0.9998
< 65	162	26 (16.0)	N.A.	143	0	N.E.	N.E.	
>= 65	170	37 (21.8)	N.A.	182	0	N.E.	N.E.	
SEX								1.0000
MALE	269	52 (19.3)	N.A.	269	0	N.E.	N.E.	
FEMALE	63	11 (17.5)	N.A.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HEPATITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								1.0000
HBV	98	15 (15.3)	N.A.	95	0	N.E.	N.E.	
HCV	27	7 (25.9)	N.A.	25	0	N.E.	N.E.	
UNINFECTED	207	41 (19.8)	N.A.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9999
PRESENT	204	42 (20.6)	N.A.	199	0	N.E.	N.E.	
ABSENT	128	21 (16.4)	N.A.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects
SLAE Category: HEPATITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.9999
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	40 (17.9)	N.A.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	23 (21.3)	N.A.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: NEPHRITIS AND RENAL DYSFUNCTION

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	5 (1.5)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	1 (0.6)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	4 (2.4)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	4 (1.5)	N.M.E.	269	0	N.E.	N.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: NEPHRITIS AND RENAL DYSFUNCTION

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	1 (1.0)	N.M.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	4 (1.9)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	3 (1.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	2 (1.6)	N.M.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: NEPHRITIS AND RENAL DYSFUNCTION

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	4 (1.8)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	1 (0.9)	N.M.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: RASH

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	51 (15.4)	N.A.	325	2 (0.6)	N.A.	27.83 (6.77, >99.99) <0.0001	
AGE								0.7139
< 65	162	22 (13.6)	N.A.	143	1 (0.7)	N.A.	20.94 (2.82, >99.99) <0.0001	
>= 65	170	29 (17.1)	N.A.	182	1 (0.5)	N.A.	35.83 (4.88, >99.99) <0.0001	
SEX								0.9848
MALE	269	40 (14.9)	N.A.	269	2 (0.7)	N.A.	22.36 (5.40, 92.55) <0.0001	
FEMALE	63	11 (17.5)	N.A.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects
SLAE Category: RASH

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9999
HBV	98	18 (18.4)	N.A.	95	2 (2.1)	N.A.	9.86 (2.28, 42.56) 0.0002	
HCV	27	4 (14.8)	N.A.	25	0	N.E.	N.E.	
UNINFECTED	207	29 (14.0)	N.A.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9096
PRESENT	204	28 (13.7)	N.A.	199	1 (0.5)	N.A.	29.59 (4.03, >99.99) <0.0001	
ABSENT	128	23 (18.0)	N.A.	126	1 (0.8)	N.A.	26.33 (3.55, >99.99) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: RASH

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.9870
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	39 (17.4)	N.A.	217	2 (0.9)	N.A.	21.06 (5.08, 87.24) <0.0001	
>= 400 NG/ML	108	12 (11.1)	N.A.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERSENSITIVITY

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	4 (1.2)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	1 (0.6)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	3 (1.8)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	3 (1.1)	N.M.E.	269	0	N.E.	N.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERSENSITIVITY

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	4 (1.9)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	3 (1.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	1 (0.8)	N.M.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERSENSITIVITY

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	1 (0.4)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	3 (2.8)	N.M.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ADRENAL INSUFFICIENCY

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	18 (5.4)	N.A.	325	0	N.E.	N.E.	
AGE								0.9999
< 65	162	10 (6.2)	N.A.	143	0	N.E.	N.E.	
>= 65	170	8 (4.7)	N.A.	182	0	N.E.	N.E.	
SEX								0.9999
MALE	269	12 (4.5)	N.A.	269	0	N.E.	N.E.	
FEMALE	63	6 (9.5)	N.A.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ADRENAL INSUFFICIENCY

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								1.0000
HBV	98	3 (3.1)	N.A.	95	0	N.E.	N.E.	
HCV	27	2 (7.4)	N.A. (13.44, N.A.)	25	0	N.E.	N.E.	
UNINFECTED	207	13 (6.3)	N.A.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								1.0000
PRESENT	204	11 (5.4)	N.A.	199	0	N.E.	N.E.	
ABSENT	128	7 (5.5)	N.A.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ADRENAL INSUFFICIENCY

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								1.0000
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	13 (5.8)	N.A.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOTHYROIDISM/THYROIDITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	62 (18.7)	N.A.	325	11 (3.4)	N.A.	6.44 (3.39, 12.24) <0.0001	
AGE								0.0552
< 65	162	35 (21.6)	N.A.	143	2 (1.4)	N.A.	17.65 (4.24, 73.44) <0.0001	
>= 65	170	27 (15.9)	N.A.	182	9 (4.9)	N.A.	3.82 (1.79, 8.13) 0.0002	
SEX								0.3910
MALE	269	46 (17.1)	N.A.	269	7 (2.6)	N.A.	7.55 (3.41, 16.74) <0.0001	
FEMALE	63	16 (25.4)	N.A.	56	4 (7.1)	N.A.	4.41 (1.47, 13.26) 0.0039	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOTHYROIDISM/THYROIDITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.8652
HBV	98	15 (15.3)	N.A.	95	2 (2.1)	N.A.	8.48 (1.93, 37.14) 0.0007	
HCV	27	4 (14.8)	N.A. (11.47, N.A.)	25	0	N.E.	N.E.	
UNINFECTED	207	43 (20.8)	N.A.	205	9 (4.4)	N.A.	5.42 (2.64, 11.13) <0.0001	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2963
PRESENT	204	39 (19.1)	N.A.	199	5 (2.5)	N.A.	8.83 (3.48, 22.43) <0.0001	
ABSENT	128	23 (18.0)	N.A.	126	6 (4.8)	N.A.	4.42 (1.80, 10.87) 0.0004	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOTHYROIDISM/THYROIDITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.3804
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	43 (19.2)	N.A.	217	6 (2.8)	N.A.	8.02 (3.41, 18.86) <0.0001	
>= 400 NG/ML	108	19 (17.6)	N.A.	108	5 (4.6)	N.A.	4.54 (1.69, 12.19) 0.0010	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOTHYROIDISM

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	46 (13.9)	N.A.	325	11 (3.4)	N.A.	4.67 (2.42, 9.02) <0.0001	
AGE								0.0630
< 65	162	26 (16.0)	N.A.	143	2 (1.4)	N.A.	12.76 (3.03, 53.78) <0.0001	
>= 65	170	20 (11.8)	N.A.	182	9 (4.9)	N.A.	2.77 (1.26, 6.09) 0.0083	
SEX								0.5139
MALE	269	33 (12.3)	N.A.	269	7 (2.6)	N.A.	5.31 (2.35, 12.01) <0.0001	
FEMALE	63	13 (20.6)	N.A.	56	4 (7.1)	N.A.	3.46 (1.13, 10.67) 0.0213	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOTHYROIDISM

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.9782
HBV	98	7 (7.1)	N.A.	95	2 (2.1)	N.A.	3.89 (0.81, 18.75) 0.0685	
HCV	27	3 (11.1)	N.A. (11.47, N.A.)	25	0	N.E.	N.E.	
UNINFECTED	207	36 (17.4)	N.A.	205	9 (4.4)	N.A.	4.47 (2.15, 9.28) <0.0001	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.3110
PRESENT	204	29 (14.2)	N.A.	199	5 (2.5)	N.A.	6.37 (2.46, 16.46) <0.0001	
ABSENT	128	17 (13.3)	N.A.	126	6 (4.8)	N.A.	3.22 (1.27, 8.18) 0.0094	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOTHYROIDISM

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.5856
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	30 (13.4)	N.A.	217	6 (2.8)	N.A.	5.45 (2.27, 13.11) <0.0001	
>= 400 NG/ML	108	16 (14.8)	N.A.	108	5 (4.6)	N.A.	3.76 (1.37, 10.29) 0.0056	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: THYROIDITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	18 (5.4)	N.A.	325	0	N.E.	N.E.	
AGE								0.9999
< 65	162	10 (6.2)	N.A.	143	0	N.E.	N.E.	
>= 65	170	8 (4.7)	N.A.	182	0	N.E.	N.E.	
SEX								1.0000
MALE	269	15 (5.6)	N.A.	269	0	N.E.	N.E.	
FEMALE	63	3 (4.8)	N.A.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: THYROIDITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	8 (8.2)	N.M.E.	95	0	N.E.	N.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	9 (4.3)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								1.0000
PRESENT	204	11 (5.4)	N.A.	199	0	N.E.	N.E.	
ABSENT	128	7 (5.5)	N.A.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: THYROIDITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.9998
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	15 (6.7)	N.A.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	3 (2.8)	N.A.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DIABETES MELLITUS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	2 (0.6)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	1 (0.6)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	1 (0.6)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	1 (0.4)	N.M.E.	269	0	N.E.	N.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DIABETES MELLITUS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	1 (0.5)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	1 (0.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	1 (0.8)	N.M.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DIABETES MELLITUS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	2 (0.9)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERTHYROIDISM

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	36 (10.8)	N.A.	325	0	N.E.	N.E.	
AGE								0.9999
< 65	162	21 (13.0)	N.A.	143	0	N.E.	N.E.	
>= 65	170	15 (8.8)	N.A.	182	0	N.E.	N.E.	
SEX								0.9998
MALE	269	25 (9.3)	N.A.	269	0	N.E.	N.E.	
FEMALE	63	11 (17.5)	N.A.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERTHYROIDISM

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								1.0000
HBV	98	12 (12.2)	N.A.	95	0	N.E.	N.E.	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E.	
UNINFECTED	207	23 (11.1)	N.A.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9999
PRESENT	204	20 (9.8)	N.A.	199	0	N.E.	N.E.	
ABSENT	128	16 (12.5)	N.A.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERTHYROIDISM

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.9999
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	22 (9.8)	N.A.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	14 (13.0)	N.A.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOPHYSITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	9 (2.7)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	4 (2.5)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	5 (2.9)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	7 (2.6)	N.M.E.	269	0	N.E.	N.E.	
FEMALE	63	2 (3.2)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOPHYSITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	1 (1.0)	N.M.E.	95	0	N.E.	N.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	7 (3.4)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	8 (3.9)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	1 (0.8)	N.M.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 9.2.1
Time to Event Analyses of Immune Medicated AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPOPHYSITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	7 (3.1)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	2 (1.9)	N.M.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
Program Name: rt-ae-tteimae-sub-ebr2618.sas

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY OTHER EVENTS OF SPECIAL INTEREST (OE0SI)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	16 (4.8)	N.A.	325	3 (0.9)	N.A.	5.39 (1.57, 18.56) 0.0027	
AGE								0.9892
< 65	162	6 (3.7)	N.A.	143	0	N.E.	N.E.	
>= 65	170	10 (5.9)	N.A.	182	3 (1.6)	N.A.	3.79 (1.04, 13.87) 0.0306	
SEX								0.9885
MALE	269	9 (3.3)	N.A.	269	3 (1.1)	N.A.	3.10 (0.83, 11.52) 0.0759	
FEMALE	63	7 (11.1)	N.A.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY OTHER EVENTS OF SPECIAL INTEREST (OE0SI)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.6978
HBV	98	2 (2.0)	N.A.	95	1 (1.1)	N.A.	2.12 (0.19, 23.46) 0.5310	
HCV	27	1 (3.7)	N.A.	25	0	N.E.	N.E.	
UNINFECTED	207	13 (6.3)	N.A.	205	2 (1.0)	N.A.	6.48 (1.46, 28.80) 0.0048	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.9639
PRESENT	204	11 (5.4)	N.A.	199	2 (1.0)	N.A.	5.32 (1.17, 24.11) 0.0154	
ABSENT	128	5 (3.9)	N.A.	126	1 (0.8)	N.A.	5.60 (0.65, 48.09) 0.0767	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY OTHER EVENTS OF SPECIAL INTEREST (OE0SI)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.2006
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	12 (5.4)	N.A.	217	1 (0.5)	N.A.	11.98 (1.56, 92.12) 0.0023	
>= 400 NG/ML	108	4 (3.7)	N.A.	108	2 (1.9)	N.A. (26.15, N.A.)	2.03 (0.36, 11.38) 0.4125	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYASTHENIC SYNDROME

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	1 (0.3)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	1 (0.6)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYASTHENIC SYNDROME

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	1 (0.5)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	1 (0.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYASTHENIC SYNDROME

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	1 (0.4)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DEMYELINATION EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	1 (0.3)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	1 (0.6)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	0	N.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DEMYELINATION EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	1 (0.5)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	1 (0.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: DEMYELINATION EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	1 (0.4)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GUILLAIN-BARRE SYNDROME

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	0	N.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	0	N.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	0	N.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GUILLAIN-BARRE SYNDROME

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	0	N.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GUILLAIN-BARRE SYNDROME

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	0	N.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PANCREATITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	9 (2.7)	N.A.	325	2 (0.6)	N.A.	4.46 (0.96, 20.77) 0.0374	
AGE								N.M.E.
< 65	162	4 (2.5)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	5 (2.9)	N.M.E.	182	2 (1.1)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	269	7 (2.6)	N.M.E.	269	2 (0.7)	N.M.E.	N.M.E.	
FEMALE	63	2 (3.2)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PANCREATITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	2 (2.0)	N.M.E.	95	1 (1.1)	N.M.E.	N.M.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	6 (2.9)	N.M.E.	205	1 (0.5)	N.M.E.	N.M.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	5 (2.5)	N.M.E.	199	2 (1.0)	N.M.E.	N.M.E.	
ABSENT	128	4 (3.1)	N.M.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PANCREATITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	5 (2.2)	N.M.E.	217	1 (0.5)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	4 (3.7)	N.M.E.	108	1 (0.9)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: UVEITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	0	N.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	0	N.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	0	N.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: UVEITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	0	N.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: UVEITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	0	N.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ENCEPHALITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	0	N.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	0	N.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	0	N.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ENCEPHALITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	0	N.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ENCEPHALITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	0	N.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYOCARDITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	3 (0.9)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	2 (1.2)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	1 (0.6)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	3 (4.8)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYOCARDITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	3 (1.4)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	3 (1.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYOCARDITIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	3 (1.3)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYOSITIS/RHABDOMYOLYSIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	4 (1.2)	N.M.E.	325	1 (0.3)	N.M.E.	N.M.E.	
AGE								N.M.E.
< 65	162	1 (0.6)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	3 (1.8)	N.M.E.	182	1 (0.5)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	1 (0.4)	N.M.E.	N.E.	
FEMALE	63	4 (6.3)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYOSITIS/RHABDOMYOLYSIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	4 (1.9)	N.M.E.	205	1 (0.5)	N.M.E.	N.M.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	3 (1.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	1 (0.8)	N.M.E.	126	1 (0.8)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: MYOSITIS/RHABDOMYOLYSIS EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	4 (1.8)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	1 (0.9)	N.M.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GRAFT VERSUS HOST DISEASE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	0	N.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	0	N.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	0	N.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GRAFT VERSUS HOST DISEASE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	0	N.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GRAFT VERSUS HOST DISEASE

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	0	N.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: AUTOIMMUNE CYTOPENIA

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	2 (0.6)	N.M.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	2 (1.2)	N.M.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	2 (0.7)	N.M.E.	269	0	N.E.	N.E.	
FEMALE	63	0	N.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: AUTOIMMUNE CYTOPENIA

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	2 (1.0)	N.M.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	2 (1.0)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: AUTOIMMUNE CYTOPENIA

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	2 (0.9)	N.M.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: AUTOIMMUNE EYE DISORDER

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	0	N.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	0	N.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	0	N.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: AUTOIMMUNE EYE DISORDER

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	0	N.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: AUTOIMMUNE EYE DISORDER

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	0	N.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: IMMUNE MEDIATED ARTHRITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	0	N.E.	325	0	N.E.	N.E.	
AGE								N.M.E.
< 65	162	0	N.E.	143	0	N.E.	N.E.	
>= 65	170	0	N.E.	182	0	N.E.	N.E.	
SEX								N.M.E.
MALE	269	0	N.E.	269	0	N.E.	N.E.	
FEMALE	63	0	N.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: IMMUNE MEDIATED ARTHRITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	0	N.E.	25	0	N.E.	N.E.	
UNINFECTED	207	0	N.E.	205	0	N.E.	N.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	0	N.E.	199	0	N.E.	N.E.	
ABSENT	128	0	N.E.	126	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 10.2.1
Time to Event Analyses of Other Events of Special Interest for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: IMMUNE MEDIATED ARTHRITIS

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	0	N.E.	217	0	N.E.	N.E.	
>= 400 NG/ML	108	0	N.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

Program Name: rt-ae-tteoesi-sub-ebr2618.sas

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY SELECT ADVERSE EVENT (SLAE)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	303 (91.3)	0.72 (0.69, 0.72)	325	269 (82.8)	1.35 (0.85, 1.41)	1.64 (1.39, 1.93) <0.0001	
AGE								0.4844
< 65	162	150 (92.6)	0.72 (0.69, 0.76)	143	116 (81.1)	1.38 (0.79, 2.10)	1.73 (1.36, 2.21) <0.0001	
>= 65	170	153 (90.0)	0.72 (0.66, 0.76)	182	153 (84.1)	1.25 (0.76, 1.48)	1.58 (1.26, 1.99) <0.0001	
SEX								0.7944
MALE	269	243 (90.3)	0.72 (0.69, 0.76)	269	221 (82.2)	1.35 (0.79, 1.48)	1.62 (1.35, 1.95) <0.0001	
FEMALE	63	60 (95.2)	0.69 (0.62, 0.76)	56	48 (85.7)	1.25 (0.72, 1.87)	1.73 (1.18, 2.55) 0.0048	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY SELECT ADVERSE EVENT (SLAE)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0979
HBV	98	82 (83.7)	0.72 (0.66, 0.79)	95	81 (85.3)	1.35 (0.79, 1.94)	1.30 (0.96, 1.78) 0.0943	
HCV	27	27 (100.0)	0.69 (0.53, 0.72)	25	21 (84.0)	1.94 (0.72, 3.71)	2.91 (1.56, 5.42) 0.0005	
UNINFECTED	207	194 (93.7)	0.72 (0.69, 0.76)	205	167 (81.5)	1.25 (0.79, 1.48)	1.74 (1.41, 2.15) <0.0001	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.2874
PRESENT	204	184 (90.2)	0.72 (0.69, 0.76)	199	159 (79.9)	1.41 (0.89, 2.10)	1.76 (1.42, 2.18) <0.0001	
ABSENT	128	119 (93.0)	0.72 (0.66, 0.76)	126	110 (87.3)	0.95 (0.72, 1.41)	1.47 (1.13, 1.91) 0.0037	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ANY SELECT ADVERSE EVENT (SLAE)

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.0514
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	211 (94.2)	0.69 (0.66, 0.72)	217	178 (82.0)	1.35 (0.89, 1.48)	1.82 (1.49, 2.23) <0.0001	
>= 400 NG/ML	108	92 (85.2)	0.76 (0.72, 0.85)	108	91 (84.3)	1.18 (0.72, 2.10)	1.32 (0.98, 1.77) 0.0621	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ENDOCRINE ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	111 (33.4)	N.A. (24.57, N.A.)	325	116 (35.7)	N.A.	0.94 (0.72, 1.21) 0.6288	
AGE								0.0662
< 65	162	61 (37.7)	N.A. (11.47, N.A.)	143	45 (31.5)	N.A. (16.36, N.A.)	1.22 (0.83, 1.79) 0.3162	
>= 65	170	50 (29.4)	N.A.	182	71 (39.0)	N.A. (12.81, N.A.)	0.74 (0.51, 1.06) 0.1042	
SEX								0.1790
MALE	269	83 (30.9)	N.A.	269	85 (31.6)	N.A.	1.01 (0.75, 1.37) 0.9424	
FEMALE	63	28 (44.4)	8.28 (3.75, N.A.)	56	31 (55.4)	2.86 (2.10, N.A.)	0.66 (0.40, 1.10) 0.1141	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ENDOCRINE ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.4367
HBV	98	28 (28.6)	N.A.	95	36 (37.9)	N.A. (9.20, N.A.)	0.74 (0.45, 1.21) 0.2273	
HCV	27	8 (29.6)	13.44 (7.36, N.A.)	25	6 (24.0)	N.A. (7.33, N.A.)	1.53 (0.53, 4.43) 0.4172	
UNINFECTED	207	75 (36.2)	N.A. (23.52, N.A.)	205	74 (36.1)	N.A.	0.99 (0.72, 1.36) 0.9480	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5196
PRESENT	204	63 (30.9)	N.A.	199	70 (35.2)	N.A. (16.36, N.A.)	0.88 (0.62, 1.23) 0.4547	
ABSENT	128	48 (37.5)	N.A. (7.36, N.A.)	126	46 (36.5)	N.A. (15.64, N.A.)	1.03 (0.69, 1.54) 0.8792	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: ENDOCRINE ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.2352
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	78 (34.8)	N.A. (24.57, N.A.)	217	74 (34.1)	N.A.	1.04 (0.76, 1.44) 0.7856	
>= 400 NG/ML	108	33 (30.6)	N.A. (11.47, N.A.)	108	42 (38.9)	N.A. (4.86, N.A.)	0.74 (0.47, 1.17) 0.2066	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GASTROINTESTINAL ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	88 (26.5)	N.A.	325	133 (40.9)	14.65 (11.24, 20.76)	0.61 (0.46, 0.79) 0.0002	
AGE								0.7177
< 65	162	42 (25.9)	N.A.	143	58 (40.6)	15.61 (10.97, N.A.)	0.57 (0.38, 0.85) 0.0057	
>= 65	170	46 (27.1)	N.A.	182	75 (41.2)	14.06 (10.38, N.A.)	0.65 (0.45, 0.93) 0.0189	
SEX								0.0555
MALE	269	66 (24.5)	N.A.	269	113 (42.0)	14.06 (11.01, 20.30)	0.53 (0.39, 0.72) <0.0001	
FEMALE	63	22 (34.9)	N.A. (11.17, N.A.)	56	20 (35.7)	15.61 (11.56, N.A.)	1.03 (0.56, 1.90) 0.9110	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GASTROINTESTINAL ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0391*
HBV	98	13 (13.3)	N.A.	95	35 (36.8)	20.76 (11.01, N.A.)	0.32 (0.17, 0.61) 0.0003	
HCV	27	5 (18.5)	N.A.	25	12 (48.0)	15.41 (5.59, N.A.)	0.36 (0.13, 1.05) 0.0503	
UNINFECTED	207	70 (33.8)	N.A. (21.52, N.A.)	205	86 (42.0)	13.37 (10.38, 20.30)	0.77 (0.56, 1.06) 0.1084	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.1251
PRESENT	204	46 (22.5)	N.A.	199	81 (40.7)	13.80 (10.97, 20.76)	0.50 (0.35, 0.72) 0.0002	
ABSENT	128	42 (32.8)	N.A. (14.36, N.A.)	126	52 (41.3)	15.87 (10.38, N.A.)	0.77 (0.51, 1.16) 0.2145	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: GASTROINTESTINAL ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.2764
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	69 (30.8)	N.A. (22.77, N.A.)	217	95 (43.8)	13.37 (10.38, 15.87)	0.65 (0.48, 0.89) 0.0072	
>= 400 NG/ML	108	19 (17.6)	N.A.	108	38 (35.2)	17.77 (11.04, N.A.)	0.48 (0.28, 0.84) 0.0082	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HEPATIC ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	175 (52.7)	4.83 (2.79, 13.37)	325	98 (30.2)	N.A.	2.23 (1.74, 2.86) <0.0001	
AGE								0.4681
< 65	162	92 (56.8)	4.21 (2.07, 10.55)	143	42 (29.4)	N.A.	2.45 (1.70, 3.54) <0.0001	
>= 65	170	83 (48.8)	10.97 (2.23, N.A.)	182	56 (30.8)	N.A.	2.03 (1.44, 2.85) <0.0001	
SEX								0.7105
MALE	269	143 (53.2)	4.30 (2.60, 13.83)	269	80 (29.7)	N.A.	2.28 (1.73, 3.00) <0.0001	
FEMALE	63	32 (50.8)	8.28 (1.45, N.A.)	56	18 (32.1)	N.A. (10.12, N.A.)	2.01 (1.13, 3.59) 0.0158	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HEPATIC ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.0221*
HBV	98	44 (44.9)	13.83 (2.92, N.A.)	95	32 (33.7)	N.A. (11.96, N.A.)	1.59 (1.01, 2.51) 0.0463	
HCV	27	23 (85.2)	0.95 (0.69, 1.48)	25	9 (36.0)	N.A. (9.00, N.A.)	6.30 (2.80, 14.17) <0.0001	
UNINFECTED	207	108 (52.2)	8.28 (2.79, 14.19)	205	57 (27.8)	N.A.	2.32 (1.68, 3.20) <0.0001	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.8732
PRESENT	204	110 (53.9)	3.68 (2.10, 12.91)	199	63 (31.7)	N.A.	2.20 (1.62, 3.01) <0.0001	
ABSENT	128	65 (50.8)	10.55 (2.60, N.A.)	126	35 (27.8)	N.A.	2.30 (1.52, 3.47) <0.0001	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HEPATIC ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.2965
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	118 (52.7)	7.26 (2.92, 13.83)	217	59 (27.2)	N.A.	2.49 (1.82, 3.41) <0.0001	
>= 400 NG/ML	108	57 (52.8)	2.76 (1.91, N.A.)	108	39 (36.1)	N.A. (10.02, N.A.)	1.89 (1.26, 2.85) 0.0019	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PULMONARY ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	13 (3.9)	N.A.	325	2 (0.6)	N.A.	6.57 (1.48, 29.21) 0.0044	
AGE								N.M.E.
< 65	162	8 (4.9)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	5 (2.9)	N.M.E.	182	2 (1.1)	N.M.E.	N.M.E.	
SEX								0.2489
MALE	269	11 (4.1)	N.A.	269	1 (0.4)	N.A.	11.30 (1.45, 87.76) 0.0035	
FEMALE	63	2 (3.2)	N.A.	56	1 (1.8)	N.A.	1.86 (0.17, 20.58) 0.6052	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PULMONARY ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	5 (5.1)	N.M.E.	95	1 (1.1)	N.M.E.	N.M.E.	
HCV	27	2 (7.4)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	6 (2.9)	N.M.E.	205	1 (0.5)	N.M.E.	N.M.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	9 (4.4)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	4 (3.1)	N.M.E.	126	2 (1.6)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: PULMONARY ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.3042
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	11 (4.9)	N.A.	217	1 (0.5)	N.A.	10.75 (1.39, 83.45) 0.0045	
>= 400 NG/ML	108	2 (1.9)	N.A.	108	1 (0.9)	N.A.	2.21 (0.20, 24.44) 0.5053	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: RENAL ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	30 (9.0)	N.A.	325	25 (7.7)	43.47 (N.A., N.A.)	1.27 (0.74, 2.18) 0.3778	
AGE								0.3089
< 65	162	8 (4.9)	N.A.	143	8 (5.6)	N.A.	0.88 (0.33, 2.35) 0.8030	
>= 65	170	22 (12.9)	N.A.	182	17 (9.3)	43.47 (N.A., N.A.)	1.60 (0.84, 3.05) 0.1510	
SEX								0.5637
MALE	269	24 (8.9)	N.A.	269	22 (8.2)	43.47 (N.A., N.A.)	1.18 (0.66, 2.12) 0.5775	
FEMALE	63	6 (9.5)	N.A.	56	3 (5.4)	N.A.	1.82 (0.45, 7.27) 0.3908	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: RENAL ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.3752
HBV	98	4 (4.1)	N.A.	95	6 (6.3)	N.A.	0.68 (0.19, 2.40) 0.5434	
HCV	27	2 (7.4)	N.A. (19.22, N.A.)	25	3 (12.0)	N.A.	0.61 (0.10, 3.64) 0.5815	
UNINFECTED	207	24 (11.6)	N.A.	205	16 (7.8)	43.47 (N.A., N.A.)	1.64 (0.86, 3.13) 0.1309	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5940
PRESENT	204	18 (8.8)	N.A.	199	16 (8.0)	N.A.	1.15 (0.59, 2.26) 0.6844	
ABSENT	128	12 (9.4)	N.A.	126	9 (7.1)	43.47 (N.A., N.A.)	1.52 (0.62, 3.74) 0.3541	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: RENAL ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.0715
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	25 (11.2)	N.A.	217	16 (7.4)	43.47 (N.A., N.A.)	1.74 (0.91, 3.30) 0.0878	
>= 400 NG/ML	108	5 (4.6)	N.A.	108	9 (8.3)	N.A.	0.54 (0.18, 1.63) 0.2668	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: SKIN ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	209 (63.0)	1.64 (1.25, 2.14)	325	159 (48.9)	9.69 (5.45, 24.80)	1.71 (1.39, 2.10) <0.0001	
AGE								0.4999
< 65	162	102 (63.0)	1.54 (0.82, 3.09)	143	73 (51.0)	9.13 (3.02, 24.80)	1.55 (1.15, 2.10) 0.0040	
>= 65	170	107 (62.9)	1.77 (1.25, 2.30)	182	86 (47.3)	11.04 (5.72, 32.82)	1.88 (1.41, 2.50) <0.0001	
SEX								0.9139
MALE	269	168 (62.5)	1.77 (1.25, 2.63)	269	130 (48.3)	9.69 (5.52, 28.06)	1.73 (1.37, 2.17) <0.0001	
FEMALE	63	41 (65.1)	1.41 (0.72, 2.17)	56	29 (51.8)	10.12 (2.33, N.A.)	1.62 (1.01, 2.61) 0.0448	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: SKIN ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								0.2823
HBV	98	64 (65.3)	0.97 (0.76, 2.10)	95	48 (50.5)	9.40 (3.32, N.A.)	1.83 (1.26, 2.67) 0.0014	
HCV	27	13 (48.1)	6.44 (0.95, N.A.)	25	15 (60.0)	6.93 (2.27, N.A.)	0.96 (0.46, 2.04) 0.9184	
UNINFECTED	207	132 (63.8)	1.77 (1.38, 2.33)	205	96 (46.8)	11.93 (4.67, N.A.)	1.77 (1.36, 2.31) <0.0001	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								0.5453
PRESENT	204	123 (60.3)	2.10 (1.41, 3.91)	199	95 (47.7)	9.69 (4.37, N.A.)	1.64 (1.25, 2.14) 0.0003	
ABSENT	128	86 (67.2)	1.25 (0.76, 1.77)	126	64 (50.8)	11.04 (2.83, 32.82)	1.84 (1.33, 2.56) 0.0002	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: SKIN ADVERSE EVENT

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								0.2094
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	147 (65.6)	1.41 (0.95, 1.94)	217	106 (48.8)	9.69 (5.45, 28.06)	1.86 (1.45, 2.40) <0.0001	
>= 400 NG/ML	108	62 (57.4)	2.86 (1.38, 6.44)	108	53 (49.1)	10.12 (2.89, N.A.)	1.42 (0.99, 2.06) 0.0593	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERSENSITIVITY/INFUSION REACTION

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
OVERALL	332	8 (2.4)	N.M.E.	325	1 (0.3)	N.M.E.	N.M.E.	
AGE								N.M.E.
< 65	162	2 (1.2)	N.M.E.	143	0	N.E.	N.E.	
>= 65	170	6 (3.5)	N.M.E.	182	1 (0.5)	N.M.E.	N.M.E.	
SEX								N.M.E.
MALE	269	7 (2.6)	N.M.E.	269	1 (0.4)	N.M.E.	N.M.E.	
FEMALE	63	1 (1.6)	N.M.E.	56	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERSENSITIVITY/INFUSION REACTION

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
DISEASE ETIOLOGY PER CENTRAL LAB								N.M.E.
HBV	98	0	N.E.	95	0	N.E.	N.E.	
HCV	27	1 (3.7)	N.M.E.	25	0	N.E.	N.E.	
UNINFECTED	207	7 (3.4)	N.M.E.	205	1 (0.5)	N.M.E.	N.M.E.	
VASCULAR INVASION AND/OR EXTRAHEPATIC SPREAD								N.M.E.
PRESENT	204	5 (2.5)	N.M.E.	199	0	N.E.	N.E.	
ABSENT	128	3 (2.3)	N.M.E.	126	1 (0.8)	N.M.E.	N.M.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.

(1) KME of median time to first AE.

(2) Hazard ratio from unstratified Cox proportional hazard model.

(3) p-value from unstratified log-rank test.

(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if ≤ 0.05).

MedDRA Version: 26.1; CTC Version 5.0

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Table 8.2.1
Time to Event Analyses of Select AE Categories for Any TEAE
By Significant Subgroup
All Treated Subjects

SLAE Category: HYPERSENSITIVITY/INFUSION REACTION

Subgroup	Nivo + Ipi			Sora / Lenva			Nivo + Ipi vs. Sora / Lenva	
	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	N	Subjects with Event n (%)	KME (95% CI) (mon) (1)	HR (95% CI) (2) P-value (3)	Test for Interaction P-value (4) (5)
BASELINE								N.M.E.
ALPHA-FETOPROTEIN								
< 400 NG/ML	224	5 (2.2)	N.M.E.	217	1 (0.5)	N.M.E.	N.M.E.	
>= 400 NG/ML	108	3 (2.8)	N.M.E.	108	0	N.E.	N.E.	

Feb 2024 DBL. Includes AEs reported between first dose and 100 days after last dose of study treatment.
(1) KME of median time to first AE.
(2) Hazard ratio from unstratified Cox proportional hazard model.
(3) p-value from unstratified log-rank test.
(4) (5) p-value for treatment*subgroup-factor interaction from an unstratified Cox proportional hazards model with treatment, subgroup factor, and treatment*subgroup-factor interaction as independent variables (marked by asterisk if <= 0.05).
MedDRA Version: 26.1; CTC Version 5.0
Program Path: /projects/bms214671/stats/market/ma9dw_202402/prog/tables
Program Name: rt-ae-tteslae-sub-ebr2618.sas